Liothyronine

Case Details with Clear Evidence that NHS England Guidance on Prescription of Liothyronine is not Being Followed by CCGs

Evidence in Response to a Request from
The Lord O'Shaughnessy
Parliamentary Under-Secretary of State
for Health and Social Care

19th October 2018

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Preface

Guidance from NHS England has specified that liothyronine (L-T3) will continue to be available on prescription in exceptional cases, in accordance with a position statement from the British Thyroid Association.

It is disappointing that such guidance is not being followed and this document, containing case studies from nationwide, provides evidence of this. The current uncertainty, with liothyronine-treated individuals either being denied ongoing prescriptions or needing to source the treatment themselves at their own cost, seems very much against patients' interests.

Following such representation, it is hoped that there will be further clarification of how guidance on liothyronine treatment will operate. Whilst the role of specialist endocrinologists in assessing exceptionality and monitoring liothyronine therapy is clear, we suggest that, similar to levothyroxine (L-T4), responsibility for prescribing liothyronine should continue to be in primary care.

The British Thyroid Association remains committed to working with the Department of Health, health professionals and patient groups to safeguard a role for liothyronine treatment in UK clinical practice.

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September 2018

The authors would like to acknowledge the support of Healthwatch Norfolk for their work with Thyroid Support Group Norfolk to try and rectify the issues in Norfolk.

Executive Summary

During the House of Lords “Regret Debate” on 20th June 2018, led by Lord Hunt of Kings Heath, Lord O’Shaughnessy, Parliamentary Under-Secretary of State at the Department of Health and Social Care, requested details of patient cases where there is clear evidence that NHS England guidance is not being followed. UK thyroid patient groups have collaborated with the British Thyroid Association (the UK thyroid specialist professional body) to produce the evidence for this dossier[1].

This evidence demonstrates that throughout the UK, NHS guidelines are not being followed locally, leading to significant harm to patients. During the above debate Lord O’Shaughnessy committed to asking NHS England for ways to clarify to CCGs the guidelines for the prescribing of liothyronine (L-T3). Clarification is also needed to determine whether the costs will be shared or will revert to the prescribing authority .

The inactive pro-hormone thyroxine (T4) is produced by the thyroid gland. T4 is then converted in the body through the process of deiodination into the active hormone tri-iodothyronine (T3). This essential process enables the body’s systems to fully function.

The standard treatment for patients diagnosed with hypothyroidism is the synthetic medication, levothyroxine (L-T4) that the body needs to convert to T3.

Liothyronine (L-T3) is the active synthetic thyroid hormone replacement - a completely different medication to levothyroxine.

Some patients have unresolved symptoms on L-T4 alone, and treatment with L-T3 is often more effective - the reasons for this are not yet fully understood. Therefore if the body does not utilise L-T4 correctly, for whatever reason, then the addition of L-T3 is the only alternative.

The latest NHS England guidance states that liothyronine should still be prescribed in exceptional cases, and that those patients established on L-T3 who continue to derive benefit from its use should continue to be prescribed L-T3.[2] [3]

Clinical Commissioning Groups (CCGs) have a statutory duty to provide reliable guidance to local clinicians. However, the patient stories and CCG response letters in this dossier will demonstrate the many CCGs who are either misinterpreting or not adhering to the NHS England guidance.

This report includes recommendations for a way forward.

A brief note on the cost of L-T3 in the UK

The UK supply of L-T3 has been subject to price increases of over 6,000% over a ten year period. The Competition and Markets Authority is currently investigating the manufacturer which, until 2017, held the sole marketing licence in this country and in 2017 provisionally found them guilty of abusing their dominant position[4].

Other European countries pay far less for this generic drug and, now that there are more manufacturers licenced to supply L-T3 to the NHS, it is to be hoped that the drug price will fall rapidly to be in line with other European markets. Since two of the providers of L-T3 to the NHS manufacture it outside the UK, we see no reason why the NHS cannot source directly from Europe if necessary. We will be monitoring price changes over the coming months and will revisit this issue if required.

Patients in the UK who have had to resort to buying L-T3 privately are not yet reporting any evidence of reducing prices at the end of the supply chain.

It is noteworthy that the dramatic increase in the cost of liothyronine has been associated with a 49 fold reduction in prescription of this drug by CCGs nationwide. This has led to a variation between CCGs of almost 5,000% in prescribing rates, which analysis reveals are lowest and have fallen most dramatically in areas where levels of deprivation are greatest. See Appendix 5.

Recommendations

The report authors respectfully make the following recommendations:

- Local guidelines for the prescribing of L-T3, which are not in line with NHS England guidance and good clinical practice, be withdrawn and local clinicians refer to clinical advice from NHS England, including giving due attention to statements in the latest guidance from the British Thyroid Association which clarifies those patients classified as exceptional.[2] [3]

- NHS Clinical Commissioners follow up the unclear guidance sent to CCGs at the end of July 2018[7], to advise that patients who are stable and well on L-T3 and wish to continue taking it, do not have their treatment disrupted.

- NHS England provide clarity on whether primary care or secondary care bear the cost for ongoing prescription of L-T3. Whilst NHS England have mandated that secondary care should oversee L-T3 therapy, they have not specified who funds it.

- Pending the introduction of any new guidelines we believe that clinicians across the country should refer to the current British Thyroid Association guidance for GPs and endocrinologists, which is included in the latest NHS England Guidance but often overlooked: "Switching your Patients from liothyronine to levothyroxine? - 2016"[3]. In particular:

    - GPs to follow the advice in the "Frequently Asked Questions for GPs" that,

      > "*Patients established on L-T3 who continue to derive benefit from its use should continue on L-T3"*

  and

    - Endocrinologists have particular regard to the statements in the "Information for Endocrinologists" that,

      > *"...we recognise that a proportion of patients on L-T4 continue to suffer with symptoms despite adequate biochemical correction and that a carefully audited trial of L-T3 under the supervision of an accredited endocrinologist might be warranted in exceptional cases. Thus, a small proportion of hypothyroid patients will be treated with L-T3 most of whom will be known to local endocrinology services. However, a fraction of patients, especially those who have been on L-T3 treatment for many years, may not attend secondary care clinics and endocrinologists may receive requests to review such patients with a view to discontinuing treatment. A small proportion of hypothyroid patients will be treated with L-T3."*

  and

> *"We wish to emphasise that the decision to continue or stop L-T3 should be based on clinical need above other considerations and that the BTA position statement should in no way be used as an endorsement for discontinuing L-T3."*

- Patients who were well on L-T3 and have had it withdrawn, have it reinstated.
- Where an NHS endocrinologist recommends a trial of L-T3 for a new patient, this goes ahead without question.
- Work commences to develop a clear patient pathway for L-T3 prescribing, incorporating input from patients and patient groups. See Appendix 3 for a suggested pathway developed by ITT, Thyroid UK, and Thyroid Patient Advocacy, which has now had further input from the Midlands Thyroid Support Group, The Thyroid Trust and the BTA, as a starting point.
- The NHS stops paying significantly more for this generic drug than it costs in other countries. If suppliers with UK licences will not make their product available at a reasonable cost, source from European suppliers.

NHS documents requiring review

National Guidance

Patient groups have had concerns for some time that local health authorities are not acting in line with national guidance in relation to L-T3 prescribing, particularly since L-T3 was included in the NHS England consultation on “Items which should not be routinely prescribed in primary care.”

The response to that consultation[2] advised on ***Liothyronine (including Armour Thyroid and liothyronine combination products*****)** as follows:

> *“Liothyronine - We received a significant number of responses during the consultation around liothyronine. The main recurring theme – particularly from patients and organisational bodies - is that liothyronine is an effective treatment which is invaluable to patient wellbeing, quality of life and condition management. We also heard that a small proportion of patients treated with levothyroxine continue to suffer with symptoms despite adequate biochemical correction. The joint clinical working group considered the consultation feedback and therefore decided that liothyronine should still be prescribed for a small cohort of patients. The joint clinical working group changed the recommendations so that initiation of prescribing of liothyronine in appropriate patients should be initiated by a consultant endocrinologist in the NHS, and that deprescribing in ‘all’ patients is not appropriate as there are recognised exceptions.”*

The guidance goes on to say, on exceptionality:

> *“...where levothyroxine has failed and in line with BTA guidance, endocrinologists providing NHS services may recommend liothyronine for individual patients....”*

Links are then provided to the BTA 2015 guidance on management of hypothyroidism and the further clarification on exceptionality from the BTA December 2016 statements on L-T3[3].

Parliamentary Scrutiny

Lord O’Shaughnessy responded to a written question from Lord Hunt on 4th July 2018, stating:

> *"the national guidelines advise clinical commissioning groups (CCGs) that local decisions should be made regarding arrangements for the on-going prescribing of liothyronine, taking into account both the local needs of the population and the best practice set out in the guidance.”* [5]

On 25th July, in response to another written question from Lord Hunt asking:

> *"...whether Her Majesty's Government intend to review local and regional guidance by NHS bodies which do not follow current national guidance in relation to the prescribing of liothyronine (T3)"*

Lord O'Shaughnessy wrote:

> *"...we are informed by NHS England that the joint clinical working group has agreed that NHS clinical commissioners will reiterate to clinical commissioning groups (CCGs) by the end of July 2018 that the intention of the guidance published last November was to end the routine prescription of liothyronine <u>only where it was clinically appropriate to do so."</u>* (our emphasis).
>
> *CCGs are accountable to NHS England, which has a key role to ensure that they, as statutory organisations, deliver the best possible services and outcomes for patients within their financial allocation. Where there are concerns about CCGs failing or at risk of failing to discharge its functions, NHS England has the ability to exercise formal powers to either provide enhanced support to a CCG, or in rare circumstances to intervene."*[6]

NHS Clinical Commissioners Statement

When we reviewed the subsequent statement sent out by NHS Clinical Commissioners, we felt it did not clarify matters as Lord O'Shaughnessy had intended. Instead we have been advised, by NHS Clinical Commissioners, that it said:

> *"As your representative body, one of the key roles we undertake on your behalf is engaging with national stakeholders and we have heard from several organisations representing thyroid patients reporting that many areas are implementing a blanket ban on Liothyronine prescribing. Whilst it is entirely for each CCG to make their own decision about the local approach that is taken, the guidance does include specific exceptionality in relation to Liothyronine. This was developed and included based on a considerable number of responses that we received to the consultation and following further discussion at the clinical working group. There is potential that CCGs will receive local challenges to blanket ban decisions based on this exceptionality, so it will be important to robustly demonstrate why the exceptionality criteria have been disregarded"*[7]

We do not see any circumstances where simply 'disregarding' the exceptionality criteria can be acceptable.

Cataloguing LT-3 Documents across the NHS

We have reviewed 146 separate L-T3 documents from across the NHS.[8]

Count	Reach	Type
12	National	Guidance, policy and information documents
103	Local	Guidance, policy and information documents
14	Local	Governing Bodies' Meetings Documentation
17	Local	Emails

Since many of the local documents are for groups of CCGs, we believe these documents provide evidence in respect of close to 100% of CCGs in England and Wales.

A lack of clarity leading to patient harm

We believe the evidence we have gathered shows conclusively that over 90% of CCGs are using guidance which is not taking into consideration the best practice in the latest NHS England guidance[2, 3] and that harm is being caused to patients.

In particular, we are concerned that the clarification in the BTA December 2016 statements on L-T3, is being overlooked. These statements form part of the latest overall NHS England guidance, but are not clearly signposted. In the 146 documents that were reviewed we found only seven that explicitly mention the key guidance these statements contain - that treatment for stable patients should not be disrupted[3].

The documents we reviewed are listed, with issues catalogued, in Appendix 2.

While NICE is in the process of developing new guidelines for thyroid disorders, we feel some of the national guidance and information we looked at could be clearer; in some instances it is also either out of date or, in the case of the PrescQIPP patient leaflet for example, may contain inaccuracies.

Furthermore, most local guidance documents do not include the clear statements set out in the BTA 2015 guidance on management of primary hypothyroidism, such as that the goal of therapy for hypothyroidism includes restoring patient well-being and not causing harm.[9]

We believe the patient stories and letters in Appendix 1 show that local health authorities are not fulfilling their duty of care to thyroid patients who require L-T3.

Very few documents reflect the BTA December 2016 clarifications on which patients may qualify for a trial of L-T3 or when it should continue to be prescribed.[3]

The most up to date NHS England national guidance, we believe, requires clarity around the definition of 'exceptional' and there is a need for the addition of a clear patient pathway and signposting to reliable sources of further information such as the BTA, rather than PrescQIPP, for example.

East of England PAC and PrescQIPP

A joint detailed review of an example liothyronine guidance document by the East of England Priorities Advisory Committee (PAC) can be found in Appendix 5. We have been particularly concerned by this document and the PrescQIPP Bulletin 121 which it appears to be based on.

The PAC describes itself as 'a function of PrescQIPP'[10]. PrescQIPP is a pharmacy led CIC organisation subscribed to and funded by its members, which are CCGs. As an independent body it is not accountable to the NHS and not subject to Freedom of Information requests.

It appears that guidance from PrescQIPP, rather than national NHS England guidance, has been used to inform CCG guidelines around the country and the NHS England guidance currently includes a link, *"for further resources and guidance for CCGs and prescribers"*, to a PrescQIPP L-T3 patient leaflet which, amongst other issues, includes an incorrect link which indicates it is going to BTA information but in fact leads only to an error page. We have detailed 53 documents referencing PrescQIPP guidance, or other unreliable sources, in the table in Appendix 2.

RMOC (South)

On the 4th July Lord O'Shaughnessy responded to a Parliamentary Question from Lord Hunt to say that:

> *"Advice developed by the Regional Medicines Optimisation Committee (South) will, be made available to CCGs to support a consistent national approach to the on-going prescribing of liothyronine." (L-T3).*

In their March 2018 minutes, RMOC (South) say they now have draft guidance which they are circulating to specialists for input before they are finalised.

However, we found only one mention in one CCG’s Meeting Minutes that they were awaiting the Regional Medicines Optimisation Committee’s “RMOC” guidance and, to the best of our knowledge, the RMOC only reached out for feedback from three patient organisations involved in the preparation of this dossier, for input into their draft document towards the end of September 2018. The BTA were not approached by RMOC and the RMOC have not yet followed up BTA’s offer to provide feedback or advice.

Outstanding Questions

In some cases, we may not have seen the most recent documents from some areas as many documents publicly available on the internet are not regularly updated, and some are not online at all, therefore we had to email some CCGs for their policies.

The table in Appendix 2 illustrates how issues are recurring across the country, but is only a snapshot. A more thorough review by the Department of Health or NHS England is needed.

We question the rationale for not having consistent up to date guidance across the NHS and we trust NHS England can now ensure all CCG and health authority policies and information documents, in respect of L-T3, are looked into and that the issues we highlight will be addressed.

We also question the monetary cost to the NHS of all of these separate sets of guidelines being produced.

The human cost is illustrated by the patient stories in the following section and Appendix 1.

Summary of patient experiences

We have been contacted by more than 400 affected patients all over the country, including some in Scotland, and have shared a small selection of the stories we have received, along with patient letters from their clinicians and local healthcare authorities, in Appendix 1.

The patients' evidence reveals the harm being done and the human impact of national guidance not being followed. These individuals - and all other affected patients - require urgent intervention in their cases. We note there will be affected patients who may not have the capacity to proactively seek help, since it is recognised that the symptoms of undertreated hypothyroidism can include an impaired cognitive function and debilitating apathy. We urge NHS England to proactively seek to protect these patients from harm.

Each of the stories has been anonymised and the patients have given their permission to be included in this dossier.

The common themes are:

- Patients who had been previously very unwell on L-T4 only, and then subsequently been stable on L-T3, either on its own or in combination with L-T4, often for several years, have been told that the NHS in their area will no longer prescribe it for them.
- The justifications for withdrawing treatment have been either cost related or because of blood test results - patients' well-being is being overlooked.
- Patients are being told the only way to prove to their CCG that they require L-T3 is for them to stop taking it and become unwell - which is counter to BTA December 2016 guidance on L-T3[3] which states that if a patient is stable, disrupting their medication can cause serious problems and is likely to be costly to rectify.
- Many described their condition as being "unable to function" on L-T4.
- When treated with L-T3, many patients reported that they "got their lives back".
- When treated with L-T4 only, many patients report they were so unwell they had to give up working.
- Many reported once taking L-T3 they were able to return to work having previously been disabled. Several specifically stated they were able to return to high performing roles.
- Many described their improved condition by saying, "I can function again".
- Many reported that, when they were not taking L-T3, they were given multiple other tests and treatments which generally did not help them but will have been expensive for the NHS.

- Many reported they felt that if they were no longer prescribed L-T3, having been stable on it for some time, it was a life or death situation. Without this medicine, which had been proven to help them so profoundly, they did not feel that their lives would be worth living.
- Patients who are having their medication withheld are either now sourcing it privately, which many can ill afford and feel very uneasy about, or are finding their health deteriorating without it, in some cases dramatically.
- Several patients have been told explicitly, sometimes in writing, by NHS endocrinologists, GPs or health authorities, that the only way they can have L-T3, which is acknowledged to help them, is by sourcing it outside the NHS as the NHS will not pay for their medication.
- Several patients have been informed that they can have a private prescription from their NHS doctor, but that the NHS will not pay for their medication.

In addition patients have reported to us that some pharmacists are refusing to fill L-T3 prescriptions and others are writing the cost of the L-T3 medication on the dispensing label which is causing patient unease.

Appendix 1

A Selection of Patient Stories with NHS or CCG Letters

Case No.	Summarised
1	An ex-senior civil servant with hypothyroidism describes how she was so ill she lost the ability to function until she was prescribed L-T3, whereupon she "got her life back". Since 2017 she has been struggling with Norfolk CCG refusal to allowed her to continue to be treated on the NHS, despite her NHS endocrinologist's support and confirmation that she could continue to be prescribed L-T3.
2	After years of poor health and little improvement on L-T4 only, this patient felt so much better on L-T3, prescribed by her GP. CCG stopped it and GP's hands have been tied. She feels abandoned by the NHS, angry and worried and has had to resort to purchasing her medicine privately. 6 NHS letters included.
3	Having been completely debilitated on L-T4 alone, L-T3 was transformative for this patient's well-being but she is now having to source privately due to a blanket ban in her area. 3 NHS letters included.
4	A new patient (in Scotland) who is very unwell and desperate to try an alternative treatment to L-T4. Both GP and endocrinologist have told her they would like to offer her a trial but are not allowed to prescribe L-T3 by CCG decree and that health boards across Scotland are all taking this position. 1 NHS letter included.
5	"What is considered well?" Patient, doctor and NHS authorities locked in stalemate. Endocrinologist prescribed L-T3 and GP took over; patient was thriving but CCG has now told them they won't continue to fund the treatment. GP is giving it on a one at a time basis rather than a repeat prescription. Patient is constantly worried it will be stopped and it sounds as though the doctor is clearly also finding the situation extremely stressful. 1 letter included along with quotes from local guidelines.

9	Taken off L-T3 abruptly by her GP, gone from size 12 - 22 and feels desperately ill after nine years of being stable and well. Shropshire CCG are not responding to her concerns, meanwhile her health is deteriorating.
10	Multiple health problems for years including fertility problems, affecting her work until L-T3 was prescribed. Now lives in fear of losing her prescription and being returned to poor health.
11	Years of extremely poor health including fertility problems and heart problems, recommended L-T3 by a leading clinician but her CCG refused it on cost. She now sources it privately and, once started on L-T3, she was pregnant within 6 weeks and is back working at a high pressure job and feels she has her life back.
12	Both endocrinologist and GP want to prescribe L-T3 but the CCG says there is no funding for it. A brief story backed up by 3 NHS letters.
18	Began to think about L-T3 after eight years of being unwell on L-T4 only. Has been taking L-T3 since April 2013 and has found it has made an “amazing difference to day to day life”. Now struggling to get it on the NHS despite NHS endocrinologist support and is having to purchase privately. Says, “I am incredulous and devastated that NHS England are trying to deprescribe L-T3 as it is essential for some hypothyroid patients like me.”

Case 1 Story

Patient statement:

I gradually developed the classic symptoms of underactive thyroid in about 1994 when I was in my late forties. I was prescribed Levothyroxine (L-T4) and quickly returned to full health.

In 2002 I developed the symptoms again but in a much more rapid and dramatic form (extreme tiredness, lethargy, mental confusion, weight gain and sensitivity to cold). I had a high-pressure role in the Civil Service and came close to being unable to function at all. A consultant endocrinologist put me on a combination of L-T4 and Liothyronine (L-T3) and I rapidly returned to full health again. I have taken 75mcg of L-T4 and 20mcg of L-T3 ever since with many positive and no adverse effects.

In 2017 my GP referred me to a consultant endocrinologist at the Norfolk and Norwich University Hospital, at the behest of the North Norfolk Clinical Commissioning Group. The consultant supervised a trial which lasted from October 2017 to mid May 2018 to attempt to 'wean' me off L-T3. L-T4 was gradually increased while L-T3 was reduced, to nil in late April and May.

During the trial all the symptoms I experienced in 2002 returned. I rapidly became mentally and physically very slow and lethargic and this time with noticeable muscle weakness and poor digestion. Particularly hard to bear was the disrupted sleep pattern: sometimes sleeping very deeply but waking very tired or hardly sleeping at all. Without wanting to be dramatic, life without L-T3 for me is no life at all. I abandoned the trial in mid-May.

I saw my consultant last week to review the trial results. She said unequivocally that she agreed that I clearly needed L-T3 and she would prescribe it if she could, but she was not able to (presumably because the CCG still embargoes it). She also confirmed that she was happy with the current combination of L-T3 (20mcg) and L-T4 (75mcg) I take.

I was very hopeful that she would be able to prescribe L-T3 as I appear to fall within the exception referred to in the NHS England Board Paper PB.30.11.2017/5[11] and following a carefully audited trial of at least 3 months duration supervised by a consultant.

Case 1 continued

The outcome of no on-going L-T3 prescription is particularly disappointing as my CCG said, in response to a Freedom of Information request, that they expected to issue guidance on exceptions by the end of January 2018.

And in response, to a letter from my MP, ------ ----, they stated in a letter of 5 March 2018 that they were 'working with local clinics to meet the outcome of the consultation with regard to the NHS Specialist Endocrinologists making the decision if this medication is needed and prescribing accordingly'. They also stated that the prescribing of L-T3 for me 'remains unchanged and the arrangements…(she)…has in place to obtain her medication should continue'.

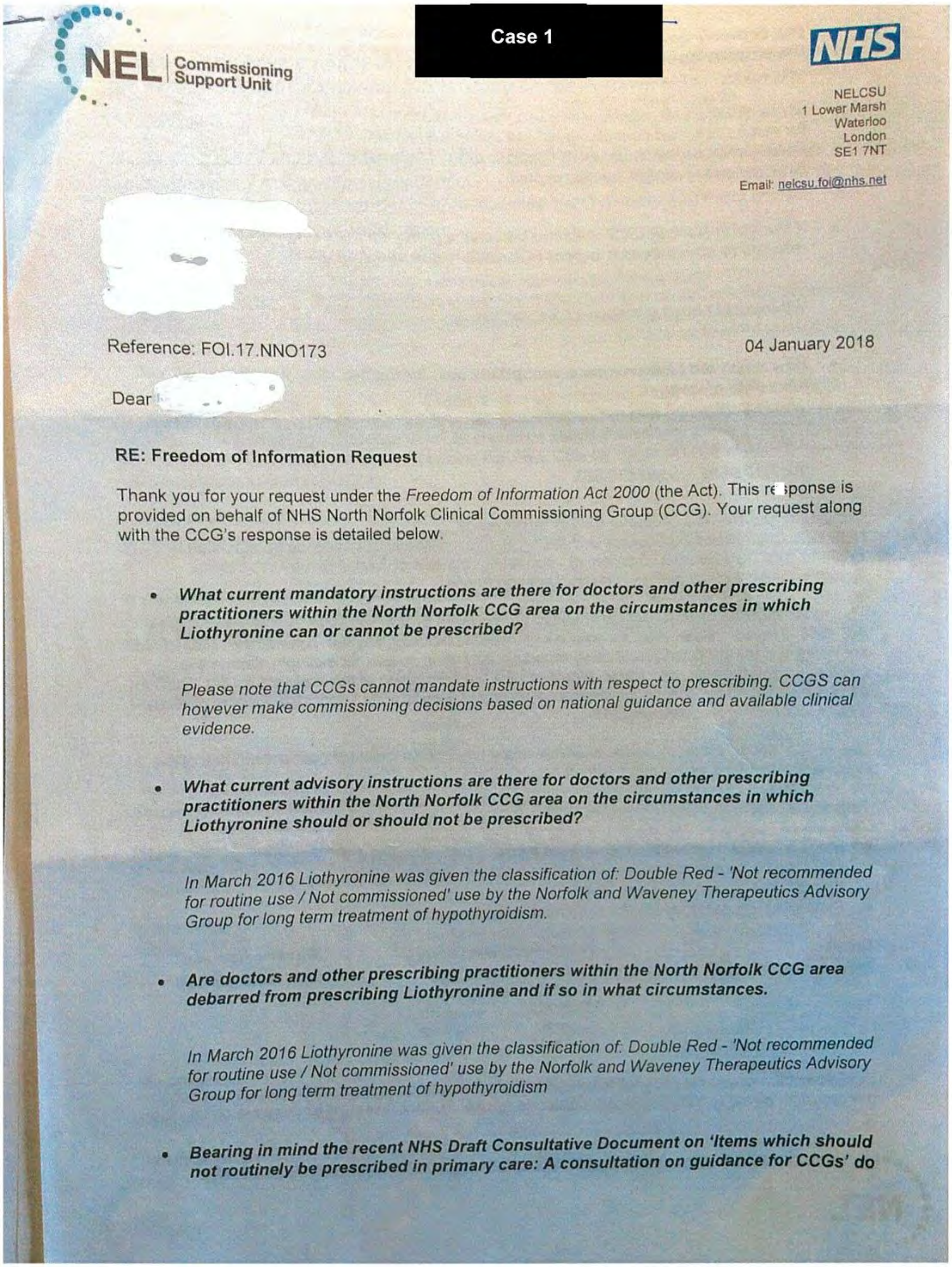
I am at a loss to understand what more I need to do to demonstrate my on-going need for L-T3 and why, in these circumstances my CCG has not implemented the NHS guidance and particularly why it is not honouring the promise it made to me.

It is difficult to explain the mental anguish all of this causes me. My health deteriorated dramatically in 2002 and I have always been fearful of the same thing happening again if L-T3 was withdrawn. The fact that the NHS consultation process recognised that there were people like me, with normal blood test results, but with real, debilitating symptoms gave me hope that my L-T3 would continue. I am now having to research private prescriptions or sourcing the drug of uncertain quality from the internet. At 71 I had hoped for a quiet retirement, but the torture continues!

7 September 2018

NHS Letter follows from Norfolk CCG:

Case 1



NEL | Commissioning Support Unit

NHS

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London
SE1 7NT

Email: nelcsu.foi@nhs.net

[redacted]

Reference: FOI.17.NNO173

04 January 2018

Dear [redacted]

RE: Freedom of Information Request

Thank you for your request under the *Freedom of Information Act 2000* (the Act). This response is provided on behalf of NHS North Norfolk Clinical Commissioning Group (CCG). Your request along with the CCG's response is detailed below.

- ***What current mandatory instructions are there for doctors and other prescribing practitioners within the North Norfolk CCG area on the circumstances in which Liothyronine can or cannot be prescribed?***

  Please note that CCGs cannot mandate instructions with respect to prescribing. CCGS can however make commissioning decisions based on national guidance and available clinical evidence.

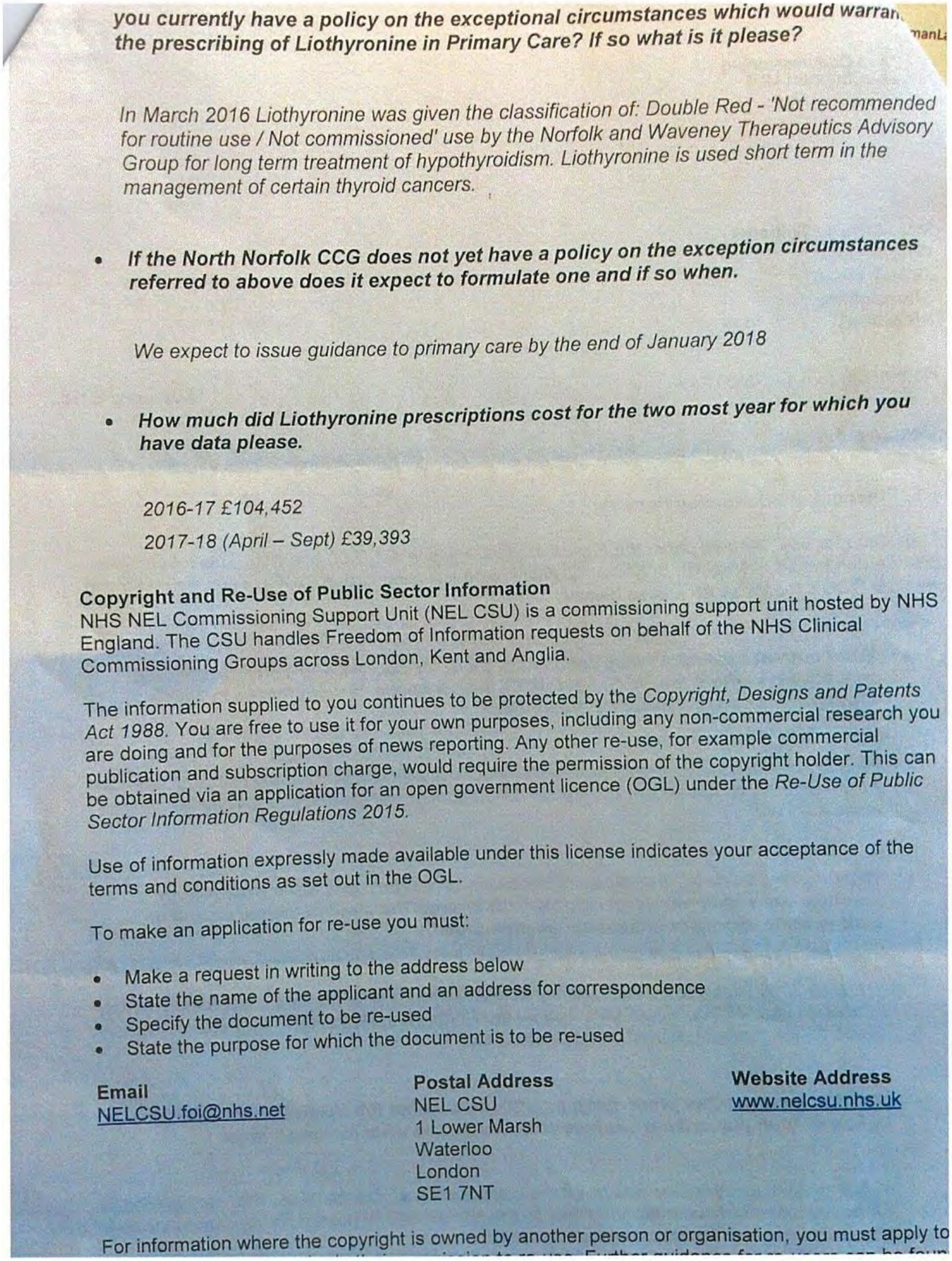
- ***What current advisory instructions are there for doctors and other prescribing practitioners within the North Norfolk CCG area on the circumstances in which Liothyronine should or should not be prescribed?***

  In March 2016 Liothyronine was given the classification of: Double Red - 'Not recommended for routine use / Not commissioned' use by the Norfolk and Waveney Therapeutics Advisory Group for long term treatment of hypothyroidism.

- ***Are doctors and other prescribing practitioners within the North Norfolk CCG area debarred from prescribing Liothyronine and if so in what circumstances.***

  In March 2016 Liothyronine was given the classification of: Double Red - 'Not recommended for routine use / Not commissioned' use by the Norfolk and Waveney Therapeutics Advisory Group for long term treatment of hypothyroidism

- ***Bearing in mind the recent NHS Draft Consultative Document on 'Items which should not routinely be prescribed in primary care: A consultation on guidance for CCGs' do***



you currently have a policy on the exceptional circumstances which would warran the prescribing of Liothyronine in Primary Care? If so what is it please?

In March 2016 Liothyronine was given the classification of: Double Red - 'Not recommended for routine use / Not commissioned' use by the Norfolk and Waveney Therapeutics Advisory Group for long term treatment of hypothyroidism. Liothyronine is used short term in the management of certain thyroid cancers.

- ***If the North Norfolk CCG does not yet have a policy on the exception circumstances referred to above does it expect to formulate one and if so when.***

We expect to issue guidance to primary care by the end of January 2018

- ***How much did Liothyronine prescriptions cost for the two most year for which you have data please.***

2016-17 £104,452

2017-18 (April – Sept) £39,393

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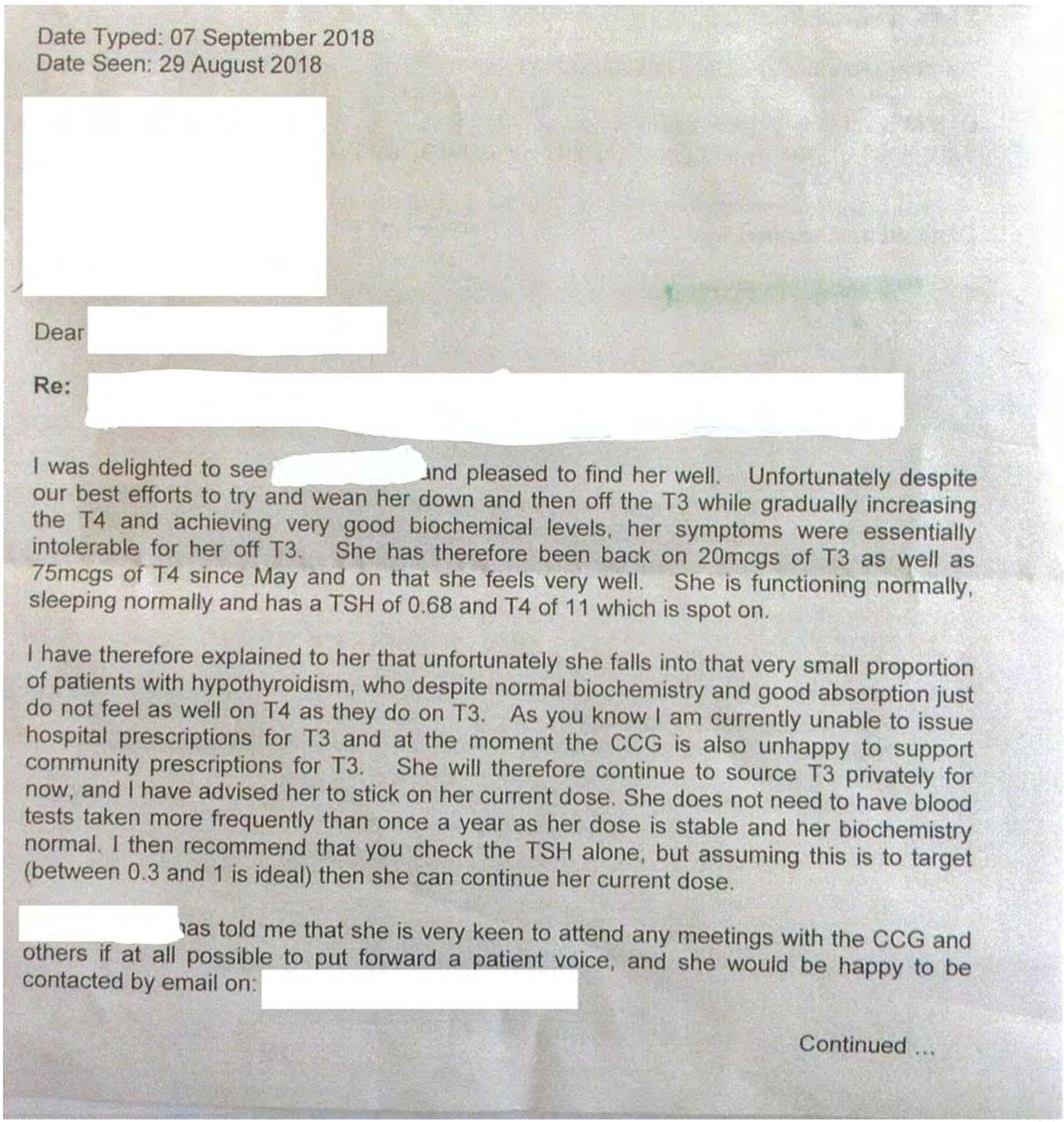
Case 1



Date Typed: 07 September 2018
Date Seen: 29 August 2018

[redacted]

Dear [redacted]

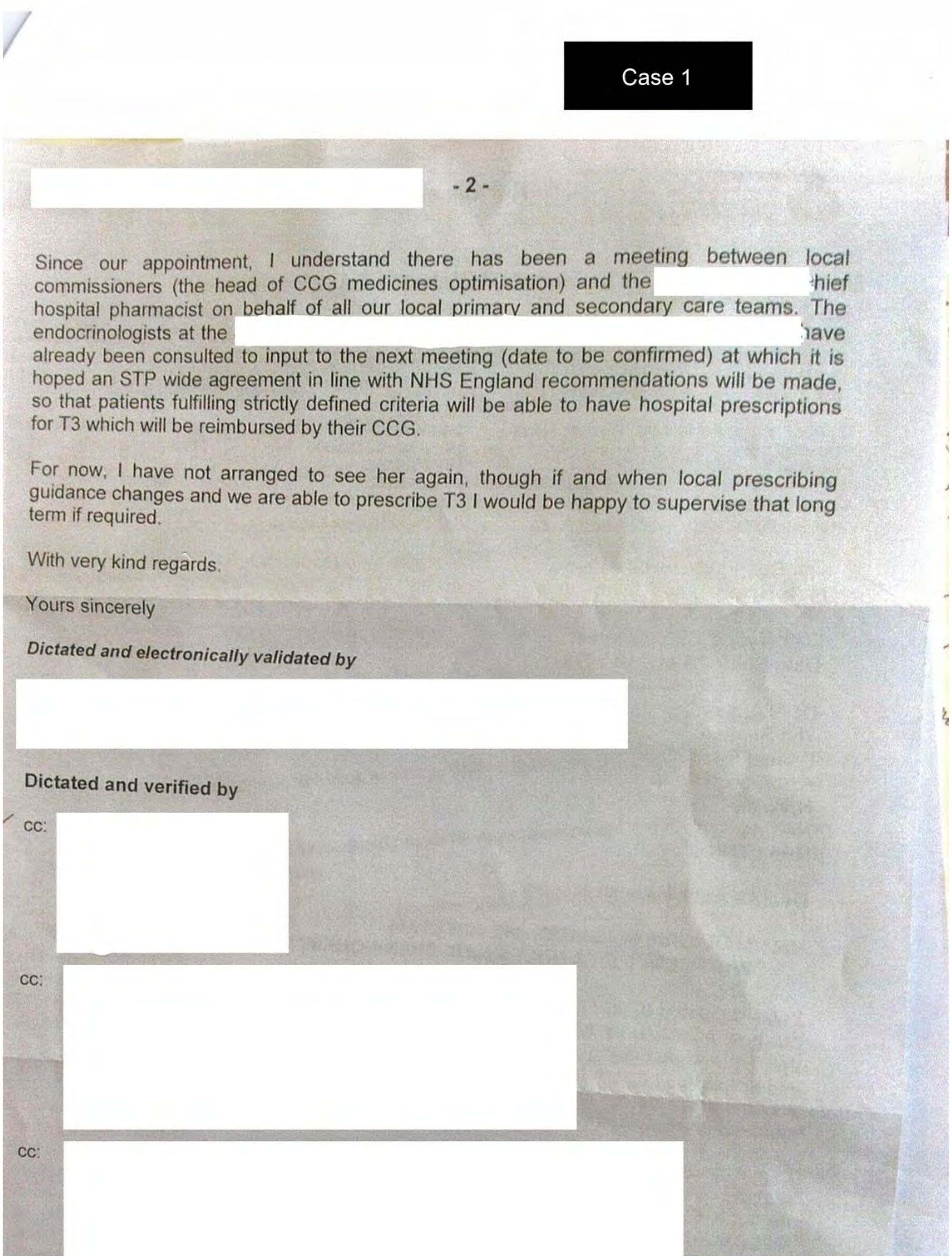
Re: [redacted]

I was delighted to see [redacted] and pleased to find her well. Unfortunately despite our best efforts to try and wean her down and then off the T3 while gradually increasing the T4 and achieving very good biochemical levels, her symptoms were essentially intolerable for her off T3. She has therefore been back on 20mcgs of T3 as well as 75mcgs of T4 since May and on that she feels very well. She is functioning normally, sleeping normally and has a TSH of 0.68 and T4 of 11 which is spot on.

I have therefore explained to her that unfortunately she falls into that very small proportion of patients with hypothyroidism, who despite normal biochemistry and good absorption just do not feel as well on T4 as they do on T3. As you know I am currently unable to issue hospital prescriptions for T3 and at the moment the CCG is also unhappy to support community prescriptions for T3. She will therefore continue to source T3 privately for now, and I have advised her to stick on her current dose. She does not need to have blood tests taken more frequently than once a year as her dose is stable and her biochemistry normal. I then recommend that you check the TSH alone, but assuming this is to target (between 0.3 and 1 is ideal) then she can continue her current dose.

[redacted] has told me that she is very keen to attend any meetings with the CCG and others if at all possible to put forward a patient voice, and she would be happy to be contacted by email on: [redacted]

Continued ...



Case 1

[redacted] - 2 -

Since our appointment, I understand there has been a meeting between local commissioners (the head of CCG medicines optimisation) and the [redacted]hief hospital pharmacist on behalf of all our local primary and secondary care teams. The endocrinologists at the [redacted]have already been consulted to input to the next meeting (date to be confirmed) at which it is hoped an STP wide agreement in line with NHS England recommendations will be made, so that patients fulfilling strictly defined criteria will be able to have hospital prescriptions for T3 which will be reimbursed by their CCG.

For now, I have not arranged to see her again, though if and when local prescribing guidance changes and we are able to prescribe T3 I would be happy to supervise that long term if required.

With very kind regards.

Yours sincerely

Dictated and electronically validated by

[redacted]

Dictated and verified by

cc: [redacted]

cc: [redacted]

cc: [redacted]

Case 2 Story

Patient statement:

I was eventually diagnosed with hypothyroidism after many years of ill health and was put on L-T4. Although initially there was some improvement, I continued to feel unwell for many years. I then consulted an endocrinologist who added L-T3 to the L-T4.

It was incredible how different I felt, my health was improved remarkably and as far as I was concerned it was a miracle pill that had given me back my life and my mind.

I was prescribed L-T3 by my NHS GP from 2007 when the cost was minimal, until November 2014 when the CCG decided that the cost was too much and that L-T4 was all they would ‘allow’ GPs or endocrinologists to prescribe. My GP was very sorry about this situation, but said her hands were tied.

I wrote to the CCG and my MP, but made no progress. I had a private blood test that showed I have a faulty gene that impairs L-T4 to L-T3 conversion, but even this was of no interest to the CCG or my GP, they were adamant they would no longer prescribe the L-T3 that I badly needed.

I have been forced into buying L-T3 from the internet ever since in order to maintain my good health. I am now managing my hypothyroidism myself with private blood tests. All the doctors have since left my GP practice so I lost my excellent GP who used to oversee my medication.

I feel completely abandoned by the National Health Service and angry that I have to buy my own medication when it should be available on the NHS. I am 68 years old and am still working, albeit part time, which I wouldn’t be able to do without L-T3. I do live with the constant worry that one day I won’t be able to obtain the medication I need via the internet, but for the time being I am enjoying my good health and leading a full life thanks to L-T3.

NHS correspondence follows:

Case 2

Lister House Surgery
Croft Way, Wiveliscombe
TAUNTON
TA4 2BF

Tel: 01984 623471
Fax: 01984 624357
e-mail:
e-mail:

Our ref: STB/SR

27th October 2014

Dear Mrs

Unfortunately I have recently received some advice from our practice pharmacist concerning your Liothyronine 20 microgram tablets: we are no longer able to issue these prescriptions as this drug is not recommended and should only be consultant prescribed.

I have, therefore, taken the Liothyronine off your repeat prescription list and I can reinstate it as a private prescription if you wish. Otherwise, I think that it may be worth trying to increase your Levothyroxine dose instead to see if this helps you. If not, it may be that we will have to refer you to secondary care to see if one of the endocrinologists would be willing to continue this treatment for you.

I am sorry that this issue has re-emerged. Please make an appointment to come and discuss it with me if you wish.

Kind regards.

Yours sincerely

@wivdocs.nhs.uk

Case 2

NHS
Somerset
Clinical Commissioning Group

Our Ref: DS/sg/474

13 February 2015

Wynford House
Lufton Way
Lufton
Yeovil
Somerset
BA22 8HR

Tel: 01935 384000
Fax: 01935 384079

enquiries@somersetccg.nhs.uk

Dear

Liothronine (T3)

Thank you for your letter of 10 February to Associate Director Head of Medicines Management concerning your supply of liothyronine (T3).

Somerset CCG aims to achieve the best clinical outcomes for its patients, in the most cost effective and evidence based manner, within the available resources for commissioning health services. For the prescribing of medication we do this through the provision of a Prescribing Formulary that is developed based upon the BNF, NICE and best practice evidence. The prescribing of medicines is primarily a matter between the prescriber and their patient and at all times prescribers in Somerset retain their clinical freedom and to make appropriate prescribing decisions. There is also an expectation that prescribers practice high quality, safe and evidence based medicine and make the best uses of the financial resources available to them in line with GMC Good Medical Practice guidance.

The role of the Somerset CCG Prescribing and Medicines Management Committee and the Somerset Prescribing Forum is to issue guidance to prescribers across primary and secondary care and ensure that due processes are followed to implement cost effective, safe and evidence based medicine.

When a medical practitioner reviews a patient's prescribed medicines, they will consider where prescribing may be outside of the local Somerset guidance and, where clinically appropriate, take steps to transfer such patients to more cost effective options. Somerset CCG encourages prescribers to ensure that during such switches of medication no harm is caused to patients because of omitted medication. Somerset CCG would also encourage prescribers to monitor the effects of such switches to ensure that patient's treatment improves as expected and does not deteriorate.

Where specialists wish to initiate medicines which Somerset CCG considers cost effective with a good safety and evidence base then Somerset has arrangements for supporting a shared care approach with the patient's GP. However, where Somerset CCG does not consider the specialist recommendation to be a cost effective use of NHS resources then Somerset CCG would not support the commissioning of the drug and

Case 2

GPs would be supported in making a different prescribing choice to the specialist recommendation. If this was not acceptable to the specialist then the specialist can use their clinical freedom to continue prescribing for their patient without an agreement to share care with the patients GP.

The situation regarding liothyronine (T3) is that Somerset CCG has historically agreed and commissioned its use in acute trusts as a short term rescue therapy for patients with severe hypothyroid episodes due to the rapid response of liothyronine. Somerset CCG has never approved the use of liothyronine as a long term maintenance therapy, a position which was agreed with local specialists. The latest guidance from the Royal College of Physicians states:

Overwhelming evidence supports the use of thyroxine (T4 or tetra-iodothyronine) alone in the treatment of hypothyroidism, with this usually being prescribed as levothyroxine. We do not recommend the prescribing of additional tri-iodothyronine (T3) in any presently available formulation including Armour Thyroid, as it is inconsistent with normal physiology, has not been unequivocally proven to be of any benefit to patients, and may be harmful.

There are potential risks from T3 therapy, using current preparations, on bone (eg osteoporosis) and the heart (eg arrhythmia). We note that the extract marketed as Armour Thyroid contains an excessive amount of T3 in relation to T4. Over-treatment with T4, when given alone, has similar risks.

Unfortunately Dr at Weston General Hospital had unbeknown to his trust and Somerset CCG initiated a small number of patients on Liothyronine (T3) for long term treatment.

Somerset CCG Prescribing and Medicines Management Committee reviewed the current prescribing and latest guidance and reiterated the position that Somerset CCG did not commission long term maintenance therapy with liothyronine, as it was not deemed to be a safe and cost effective use of NHS resources. The December 2014 NHS drug tariff price for 28 liothyronine 20 microgram tablets was £102.30 for 28 tablets and this will again increase to £152.18 from March 2015. Maintenance therapy with a 60mcg liothyronine would therefore cost the NHS budget £5400 per year compared to £25 for a patient prescribed Levothyroxine 100mcg. It was therefore recently agreed that liothyronine would be formally made a RED drug for specialist acute use only, in the Somerset CCG traffic light guidance.

Following review, the Somerset CCG guidance on liothyronine was communicated to GP practices and local secondary care colleagues. The expectation of the Somerset Prescribing and Medicines Management Committee was that GPs would review patients and convert their treatment over to levothyroxine and that specialists would support this process and also not initiate any new patients on liothyronine. No guidance has been given to abruptly cease treatment.

As with any drug GPs in Somerset retain their clinical freedom and specialist working in acute trusts may make applications for individual funding in exceptional circumstances for drugs not formally commissioned. Somerset CCG is fully supportive of GPs such as Dr addressing clinical need and we believe the Somerset CCG guidance on [redacted] **Case 2**

prescribing levothyroxine for maintenance therapy, rather than liothyronine, to be the most cost effective use of limited NHS resources.

In light of the guidance from the Royal College of Physicians and the Somerset Formulary position the recommendation is that hypothyroidism can be most cost effectively managed with levothyroxine alone.

I would encourage you to have a consultation with Dr   to consider the best option for you in the light of the above advice.

Yours sincerely

Managing Director

Copy:

Dr   , Lister House Surgery

Case 2 [redacted]

LETTER FROM DR

Weston Area Health NHS
NHS Trust

ENDOCRINOLOGY & DIABETES DEPARTMENT
WESTON GENERAL HOSPITAL
Grange Road, Uphill
Weston-super-Mare
Somerset
BS23 4TQ
Tel: 01934 636363
Direct Line: 01934 647250
Direct Fax: 01934 647209
Website: http://www.waht.nhs.uk/

CONSULTANT – Dr
CONSULTANT – Dr
CONSULTANT – Dr
CONSULTANT - Dr
DIABETES SPECIALIST NURSE -
LEAD DIABETES SPECIALIST NURSE –

Our Ref: **PS/da**
Hospital No:
NHS No:
Date of clinic: **31/07/2015**
Date typed: **10/08/2015**

Private & Confidential

Lister House Surgery
Croft Way
Wiveliscombe
Taunton
TA4 2BF

Dear

Re:

Many thanks for asking me to see who I saw previously a few years ago at Taunton.

I remember that I commenced her on T3 and she really felt better and improvement was sustained for many years.

Since it was decided to stop her primary care prescription of T3 she had to revert to buying it through the internet and she feels that the improvement has taken a dip and some of the symptoms are back again.

Her current medication is T4 75mcgs and T3 25mcgs.

She is not on any other medications.

Her general health is reasonable.

She gave me a lot of paperwork including all the results and I can see that she had DIO2 gene testing which has suggested that she is unable to convert T4 to T3 as she has a mutation in the gene. Therefore she would benefit from T3 and that could be the reason why the improvement in her with T3 is sustained.

[redacted]

Case 2

I am checking her vitamin D and vitamin B12 along with thyroid functions.

I will be copying this letter to our DTC chair Dr. to see whether the hospital, given the fact that she has a mutation in the gene, would allow T3 to be prescribed from the hospital.

I will see her again in 4 weeks time.

Yours sincerely

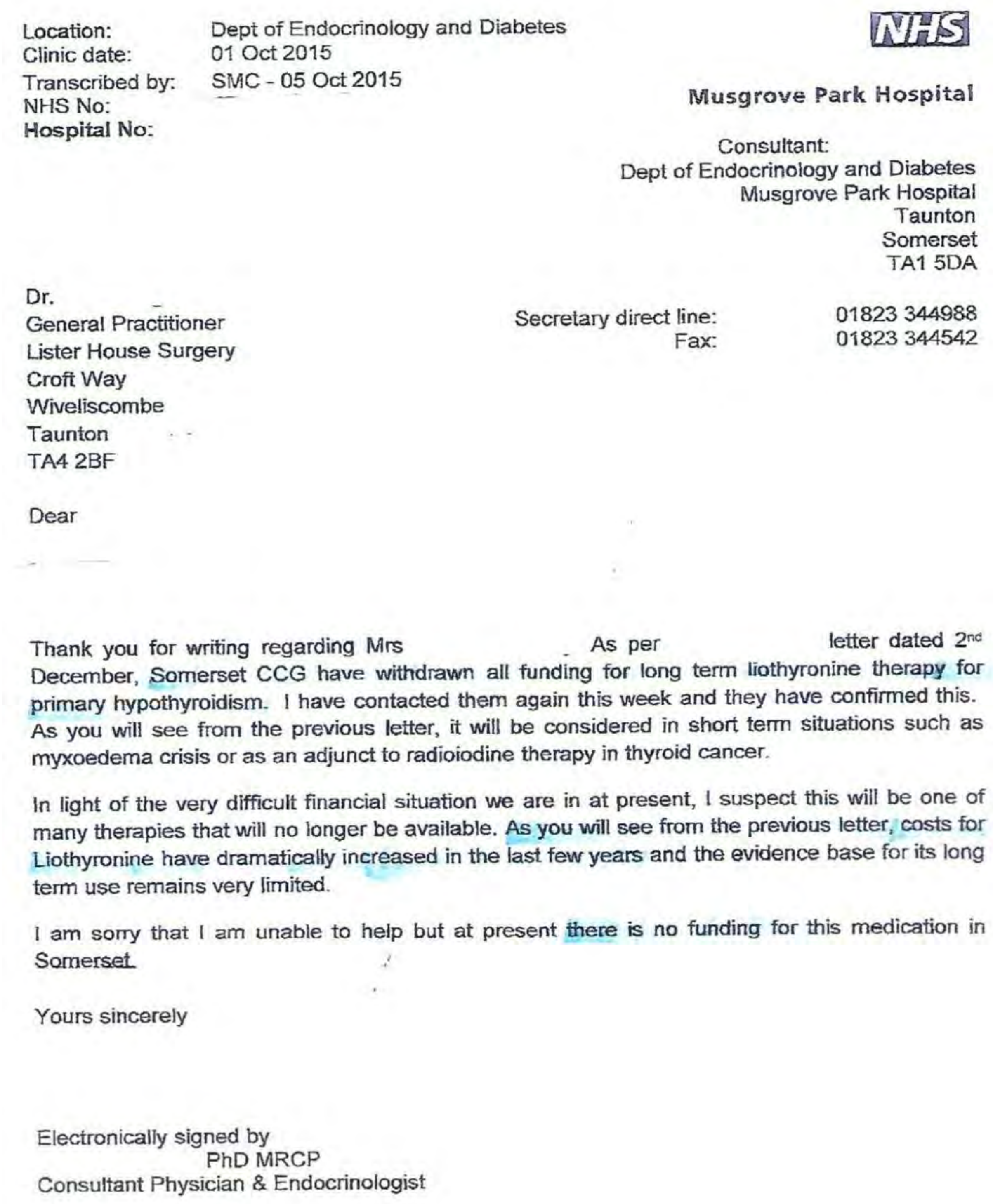
Dictated but not signed to speed delivery

Dr.
Consultant in Diabetes and Endocrinology

CC:

c.c. Dr.
Chair, DTC, WGH

Case 2



Location: Dept of Endocrinology and Diabetes
Clinic date: 01 Oct 2015
Transcribed by: SMC - 05 Oct 2015
NHS No:
Hospital No:

NHS
Musgrove Park Hospital

Consultant:
Dept of Endocrinology and Diabetes
Musgrove Park Hospital
Taunton
Somerset
TA1 5DA

Secretary direct line: 01823 344988
Fax: 01823 344542

Dr.
General Practitioner
Lister House Surgery
Croft Way
Wiveliscombe
Taunton
TA4 2BF

Dear

Thank you for writing regarding Mrs . As per letter dated 2nd December, Somerset CCG have withdrawn all funding for long term liothyronine therapy for primary hypothyroidism. I have contacted them again this week and they have confirmed this. As you will see from the previous letter, it will be considered in short term situations such as myxoedema crisis or as an adjunct to radioiodine therapy in thyroid cancer.

In light of the very difficult financial situation we are in at present, I suspect this will be one of many therapies that will no longer be available. As you will see from the previous letter, costs for Liothyronine have dramatically increased in the last few years and the evidence base for its long term use remains very limited.

I am sorry that I am unable to help but at present there is no funding for this medication in Somerset.

Yours sincerely

Electronically signed by
PhD MRCP
Consultant Physician & Endocrinologist

Case 2

Location: Dept of Endocrinology and Diabetes
Clinic date: 22 Oct 2015
Transcribed by: 27 Oct 2015
NHS No:
Hospital No:

NHS

Musgrove Park Hospital

Consultant:
Dept of Endocrinology and Diabetes
Musgrove Park Hospital
Taunton
Somerset
TA1 5DA

Secretary direct line: 01823 344988
Fax: 01823 344542

PRIVATE AND CONFIDENTIAL

Dear Mrs.

I spoke to your son on the telephone today. I understand that you have been struggling with your health following the withdrawal of Liothyronine in Somerset and have felt unwell taking levothyroxine. You are considering trying dessicated thyroid extract as an alternative therapy option. This contains a component of liothyronine (T3). Your son was keen to discuss with me what blood monitoring would be appropriate for somebody commencing this form of thyroid therapy. We agreed that if you do decided to take dessicated thyroid extract, I should see you in my clinic to check that the levels in your blood are safe. I can see from our computer that you've had a low TSH since 2012, although have not seen any test results since September 2014. It may well be you've had these taken out of area.

Natural dessicated thyroid contains approximately 38mcg of T4 and 9mcg of T3 in each 60mg grain. Most patients start 1 grain of dessicated thyroid extract and given that you were taking 10-20mcg a day of Liothyronine this would seem an appropriate dose to commence. I'd recommend having thyroid blood tests taken at your GP Practice immediately before starting the dessicated thyroid extract and then again the week before you come to see me in outpatients. I am sure your GP will be happy to arrange this.

I will send you an appointment for the New Year so that we can see how you're getting on with this therapy and determine if you're on the correct dose. I'm sure you'll be aware that it takes some time to adjust from one thyroid medication to another. I advise my patients to expect this process to take around 3-6 months. However, given that you felt so well on your Liothyronine in past, I have every expectation that you will feel well on the dessicated thyroid extract. It has a higher portion of T3 in it that is physiologically normal and to that end, I suspect it will be well

Case 2

matched against the therapy that you have been taking so far. Once your blood tests are stable on the new regime, you GP will be able to provide monitoring longer term.

I look forward to meeting you in clinic. If you decide not to try the dessicated thyroid extract, please let my secretary know so that we can cancel the appointment. For confidentiality reasons, I have not forwarded this letter to your son. I'd be grateful if you could let him know that you have received my letter so that he knows that I have followed up on our conversation.

Yours sincerely

Electronically signed by
Dr PhD MRCP
Consultant Physician & Endocrinologist

Distribution:
(Patient) — post
Dr. General Practitioner (GP) — electronic distribution
Dr. General Practitioner — electronic distribution
Copy for case notes

Case 2

Sent: 22 October 2015 11:02
To: @tst.nhs.uk
Cc: Enquires@somersetccg.nhs.uk
Subject: patient response to letter regarding hypothyroid management with combination T4/T3

Dear

Please could you forward this to Dr who recently sent my mother a letter ruling out any possibility of restarting combination therapy T4/T3. I have also copied in the Somerset CCG who also wrote to mother to explain the financial implications of continued treatment with combination therapy.

I am a consultant intensivist at Guy's and St Thomas' NHS Foundation trust.

I am writing to express my dismay regarding the treatment of my mother by the Somerset CCG and Dr

First I would like to summarise events:

My mother was diagnosed with hypothyroidism 14yrs ago and commenced on monotherapy levothyroxine. However, persistent symptoms led her to be referred to Dr who about 7 years ago decided to trial combination therapy with the introduction of liothyronine 20mcg od (this approach is now endorsed by the British and European Society of endocrinologist see attachment). This had a dramatic effect on my mother's symptoms and she remained symptom free until the liothyronine was abruptly discontinued for financial reasons and a perceived lack of evidence last year.

My mother has since tried to argue her case via the usual channels of her GP and specialist opinion of Dr to the CCG. However, there has been the repeated assertion from the Somerset CCG (managing director for the Somerset CCG wrote a letter in February 2015) and now Dr that it is reasonable to discontinue her liothyronine due to the limited evidence and financial constraints of the Somerset CCG.

My mother's health has been terrible for the last year. She has stopped working part-time and is a shadow of her former self physically, mentally and emotionally. She is now planning to embark on a trial of self-medicating with NDT, which concerns me greatly.

I have contacted Professor at Cardiff University to ask for advice and he sent me the latest guidance on the management of hypothyroidism. Please see his email below. In his email he makes the following statement:

These guidelines echo the American and European guidelines which discourage the use of T3 as first line treatment, and emphasise the potential risks, but support the trial of T3 in selected patients under careful expert supervision.

My mother has already had a trial of T3 spanning 7 years with great success. More importantly we have amply demonstrated this success with the return of symptoms having discontinued treatment (without her consent).

Case 2

My mother's case highlights the post code lottery of NHS care with Endocrinologists at Guy's and St Thomas' confirming to me that they do trial patients on t3 and have the support from the local CCG, because it's such a small percentage of patients and improvement in symptoms is well recognised.

I am very dismayed at the handling of my mother's treatment for her hypothyroidism. I completely understand the present burden on NHS finances. The arguments presented to date neglect to acknowledge that my mother has had a successful trial of t3. She is not T3 naive and is not requesting to try combination therapy for the first time merely to continue an establish effective treatment regimen. It seems morally reprehensible to stop a successful therapy backed by the expert opinion of the British, European and Endocrinology societies.

I am most concerned that my mother feels so let down and desperate to regain her life free of the symptoms she has been plagued by over the last year that she is willing to contemplate unsupervised therapy with NDT.

My letter here is to serve notice of my frustration at her treatment over this matter and I will continue to pursue this as I believe it is in her best interests.

I would appreciate a complete re-evaluation regarding the position of the prescribing t3. I also request regular specialist follow up and monitoring of her hypothyroidism given the poor symptom control.

I apologise for the long email, but I request a response from both Dr and from the Somerset CCG.

Yours sincerely

Consultant Critical Care GSTT
MBBS MRCP MD(Res) EDIC FFICM

Case 2

Dictated date
Transcribed by IM -
09 Dec 2015

NHS No
Hospital No

NHS

Musgrove Park Hospital

Consultant:
Dept of Endocrinology and Diabetes
Musgrove Park Hospital
Taunton
Somerset
TA1 5DA

Secretary direct line 01823 344988
Fax 01823 344542
@tst.nhs.uk

PRIVATE AND CONFIDENTIAL

Dear Mrs.

In answer to your recent letter, the decision to withdraw funding for T3 in Somerset is a CCG decision and has not been made by myself or by Taunton and Somerset NHS Foundation Trust. I specifically contacted the CCG when you first wrote to me and they confirmed again that they no longer fund long-term T3 replacement for hypothyroidism. As you point out in your letter, I am free to prescribe T3 if it is clinically indicated. However, as there is no funding for the medication, you would still need to pay for the drug. This would mean that I issue a private prescription and as I am full time NHS doctor, that becomes impractical.

If you chose to self-fund desiccated thyroid extract or T3/T4 combinations, I am happy to see you in clinic to check your levels are appropriate and physiological. Your son did not pressurise me to do this; I offered it quite willingly. The team here are committed to providing excellent standards of endocrine care and we are very proud of our department and our hospital. We offer the very best care we can within the limitations we have upon us.

I am sorry that I am not able to provide you with T3 funded by the NHS. I cannot enter into further discussions with you on this topic as I cannot change the situation. I hope that I will meet you in January so that we can check that your current replacement is at the safest levels. If you do not wish to see me in January, just let the PALS team know and they will cancel the appointment.

Best wishes

Case 2

Yours sincerely

Electronically signed by
PhD MRCP
Consultant Physician & Endocrinologist

Distribution:
(Patient) — post
Dr. General Practitioner (GP) — electronic distribution
PALS Team, Old Building — post
Somerset CCG, Somerset Clinical Commissioning Group — post
Copy for case notes

PALS Team
Old Building
Musgrove Park Hospital
Taunton
Somerset
TA1 5DA

Somerset CCG
Somerset Clinical Commissioning Group
Somerset Pct
Wynford House
Lufton Way
Lufton
Yeovil
BA22 8HR

Case 3 Story

Patient statement:

“Like thousands of other UK patients, I cannot have a prescription for L-T3 from my GP or my endocrinologist. I am left in a frightening place.

1990 - I was given Radioactive Iodine treatment for hyperthyroidism; this subsequently made me hypothyroid. I was prescribed L-T4, functioning well on it for 24 years.

2014 - Everything began changing. I became extremely ill with many symptoms including pain, but my worst symptom was utter overwhelming exhaustion. I was often too weak to stand unsupported; I was breathless doing most things; I could not cook, do housework or go shopping; I spent much of my days lying down; I developed hypoglycaemia; my cholesterol went very high; I lost lots of hair; I had such ‘brain fog’ that I could not take in what people said to me; I was unable to drive more than a couple of miles, as I couldn’t think what to do with the controls or what to do on the road; I cancelled holidays as it was too exhausting even to sit in a car; I was unable to visit my 97 year old mum to help her (this upsets me greatly, as she died soon after I was finally well). If I hadn’t already retired, I would have had to resign my job. This continued for nearly 2 years.

My GP referred me to 3 consultants; I pressed the third to let me try L-T3, as I realised that my L-T3 level blood results were very low, despite my high level of L-T4.

May 2016 - My GP gave me a 4-week NHS trial of L-T3. I got my life back - a life-changer.

June 2016 - Despite agreeing that L-T3 was working for me, my GP was stopped from prescribing more L-T3 by South Norfolk CCG, due to the cost to the NHS. I had previously mentioned that it was available cheaply from Europe; he apologised and said I would have to do that in future. I am forced to buy it online from abroad - and trust that the tablets are genuine.

2017 - My NHS endocrinologist was interested in my private test showing I have a defective DIO2 gene, so I do not properly convert L-T4 to the active L-T3. He took my case to the hospital board, but they would not reinstate my L-T3 prescription. He appears sympathetic and agrees that I need L-T3, but seems reluctant to put that in writing. He is very concerned that I am buying L-T3 online, but says he is still unable to prescribe it. Yet I cannot function without it.

From 2016 - All Norfolk CCGs ‘double red-tagged’ L-T3, meaning it cannot be prescribed for hypothyroidism in secondary or primary care.

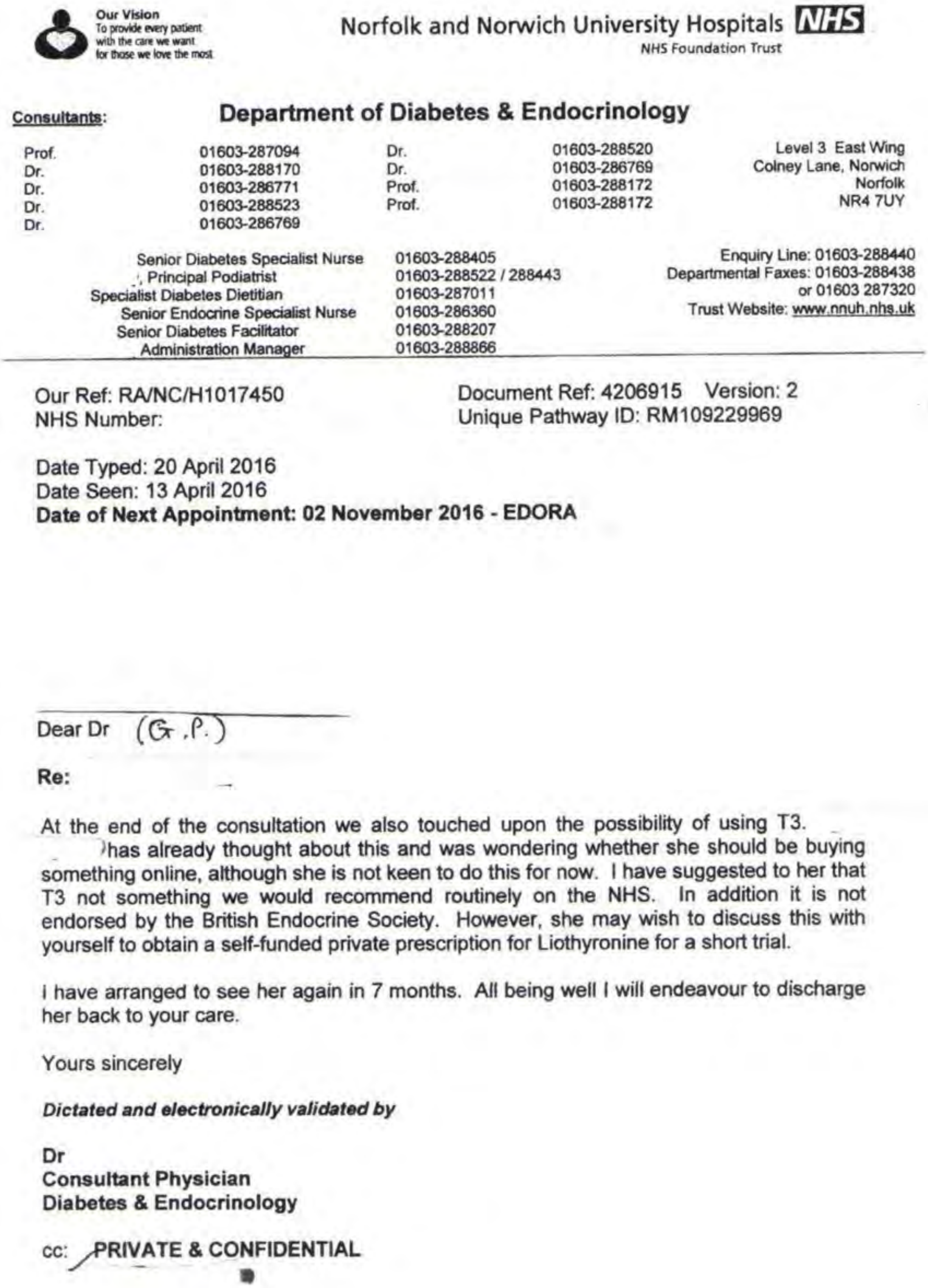
Case 3 continued.

As a member of Thyroid Support Group Norfolk, we have met the CCGs twice to discuss this; but they have not yet made a decision
on L-T3 since the NHSE Consultation recommendations of November 2017. After we saw the document one committee had written concerning L-T3, we submitted a critique of it to their next committee, as the evidential document contained many errors, and quoted several superseded statements from eg British Thyroid Association. We believe it has been discussed by four committees, but we cannot ascertain any of their decisions.

Since June 2016 – Now self-medicating on L-T3, I work as a school governor, part-run my local choir, help look after twin toddler granddaughters, run my home and contribute greatly to the Thyroid Campaign both locally and nationally. I need far fewer doctors' appointments. Some patients need L-T3 to have quality of life, and to contribute to society – I am one of them."

NHS correspondence follows:

Case 3



Our Vision
To provide every patient
with the care we want
for those we love the most

Norfolk and Norwich University Hospitals **NHS**
NHS Foundation Trust

Consultants:

Department of Diabetes & Endocrinology

Prof.	01603-287094	Dr.	01603-288520	Level 3 East Wing
Dr.	01603-288170	Dr.	01603-286769	Colney Lane, Norwich
Dr.	01603-286771	Prof.	01603-288172	Norfolk
Dr.	01603-288523	Prof.	01603-288172	NR4 7UY
Dr.	01603-286769			

Senior Diabetes Specialist Nurse	01603-288405	Enquiry Line: 01603-288440
, Principal Podiatrist	01603-288522 / 288443	Departmental Faxes: 01603-288438
Specialist Diabetes Dietitian	01603-287011	or 01603 287320
Senior Endocrine Specialist Nurse	01603-286360	Trust Website: www.nnuh.nhs.uk
Senior Diabetes Facilitator	01603-288207	
Administration Manager	01603-288866	

Our Ref: RA/NC/H1017450
NHS Number:

Document Ref: 4206915 Version: 2
Unique Pathway ID: RM109229969

Date Typed: 20 April 2016
Date Seen: 13 April 2016
Date of Next Appointment: 02 November 2016 - EDORA

Dear Dr (G.P.)

Re:

At the end of the consultation we also touched upon the possibility of using T3. has already thought about this and was wondering whether she should be buying something online, although she is not keen to do this for now. I have suggested to her that T3 not something we would recommend routinely on the NHS. In addition it is not endorsed by the British Endocrine Society. However, she may wish to discuss this with yourself to obtain a self-funded private prescription for Liothyronine for a short trial.

I have arranged to see her again in 7 months. All being well I will endeavour to discharge her back to your care.

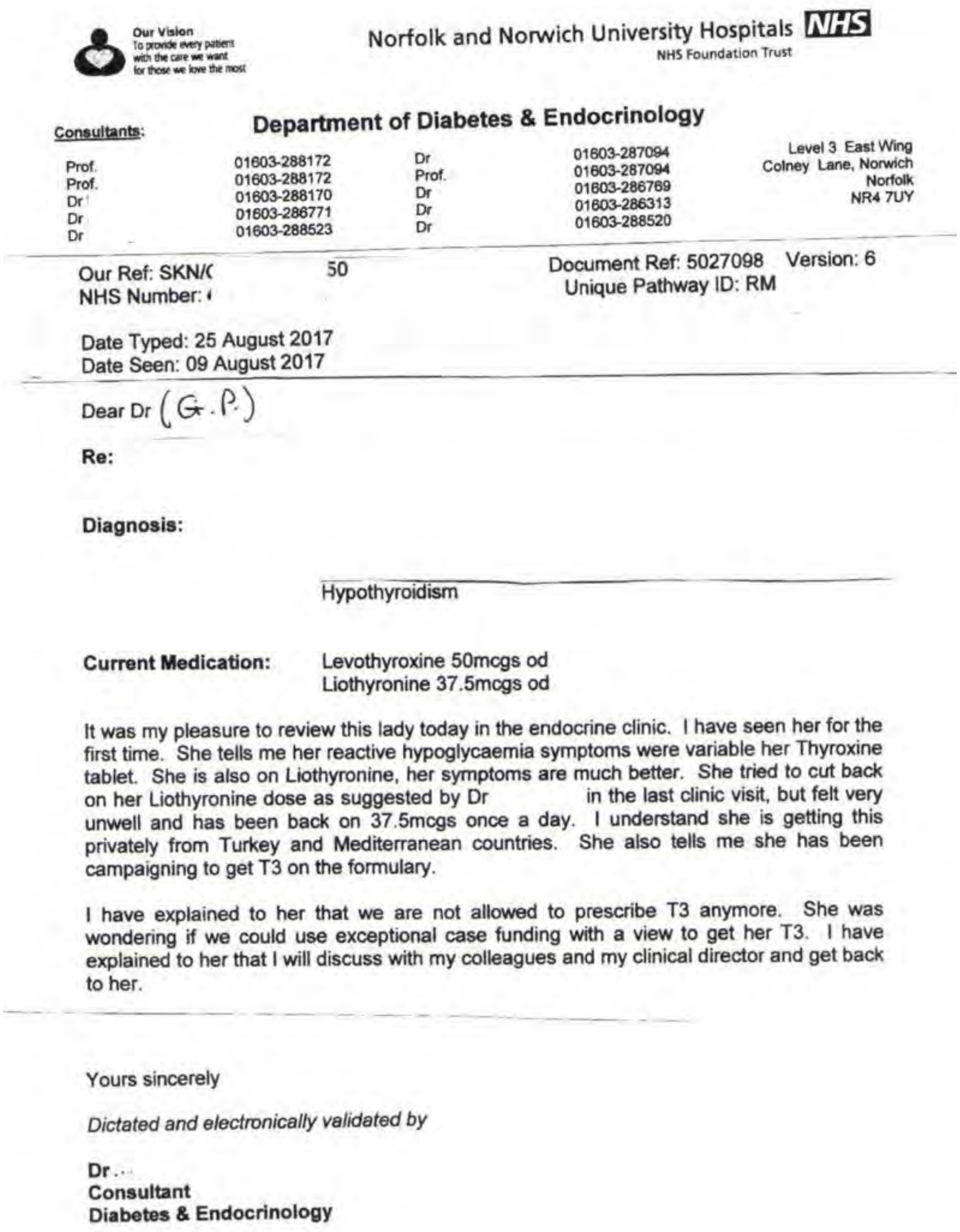
Yours sincerely

Dictated and electronically validated by

Dr
Consultant Physician
Diabetes & Endocrinology

cc: **PRIVATE & CONFIDENTIAL**

Case 3



Our Vision
To provide every patient
with the care we want
for those we love the most

Norfolk and Norwich University Hospitals **NHS**
NHS Foundation Trust

Department of Diabetes & Endocrinology

Consultants:

Prof.	01603-288172	Dr	01603-287094
Prof.	01603-288172	Prof.	01603-287094
Dr	01603-288170	Dr	01603-286769
Dr	01603-286771	Dr	01603-286313
Dr	01603-288523	Dr	01603-288520

Level 3 East Wing
Colney Lane, Norwich
Norfolk
NR4 7UY

Our Ref: SKN/(50
NHS Number: (

Document Ref: 5027098 Version: 6
Unique Pathway ID: RM

Date Typed: 25 August 2017
Date Seen: 09 August 2017

Dear Dr (G.P.)

Re:

Diagnosis:

Hypothyroidism

Current Medication: Levothyroxine 50mcgs od
Liothyronine 37.5mcgs od

It was my pleasure to review this lady today in the endocrine clinic. I have seen her for the first time. She tells me her reactive hypoglycaemia symptoms were variable her Thyroxine tablet. She is also on Liothyronine, her symptoms are much better. She tried to cut back on her Liothyronine dose as suggested by Dr in the last clinic visit, but felt very unwell and has been back on 37.5mcgs once a day. I understand she is getting this privately from Turkey and Mediterranean countries. She also tells me she has been campaigning to get T3 on the formulary.

I have explained to her that we are not allowed to prescribe T3 anymore. She was wondering if we could use exceptional case funding with a view to get her T3. I have explained to her that I will discuss with my colleagues and my clinical director and get back to her.

Yours sincerely

Dictated and electronically validated by

Dr .
Consultant
Diabetes & Endocrinology

Case 3

Our Vision
To provide every patient
with the care we want
for those we love the most

Norfolk and Norwich University Hospitals **NHS**
NHS Foundation Trust

Department of Diabetes & Endocrinology

Consultants:

Prof.	01603-288172	Dr	01603-286769	Level 3 East Wing
Prof.	01603-288172	Prof.	01603-287094	Colney Lane, Norwich
Dr	01603-288170	Dr	01603-286769	Norfolk
Dr	01603-286771	Dr.	01603-286312	NR4 7UY
Dr	01603-288523	Dr	01603-288520	

Our Ref: SKN/
NHS Number:

Document Ref: 5293164 Version: 3
Unique Pathway ID: RM

Date Typed: 07 February 2018
Date Seen: 06 December 2017
Date of Next Appointment: 18 April 2018 – EDOSKN

Dear Dr (G P.)

Re:

I am resending this letter as the original dictation done at the time of clinic was lost. I do apologise for the delay in writing this clinic letter again.

Diagnosis:

1. Hypothyroidism
2. Reactive hypoglycaemia

Current Medication:

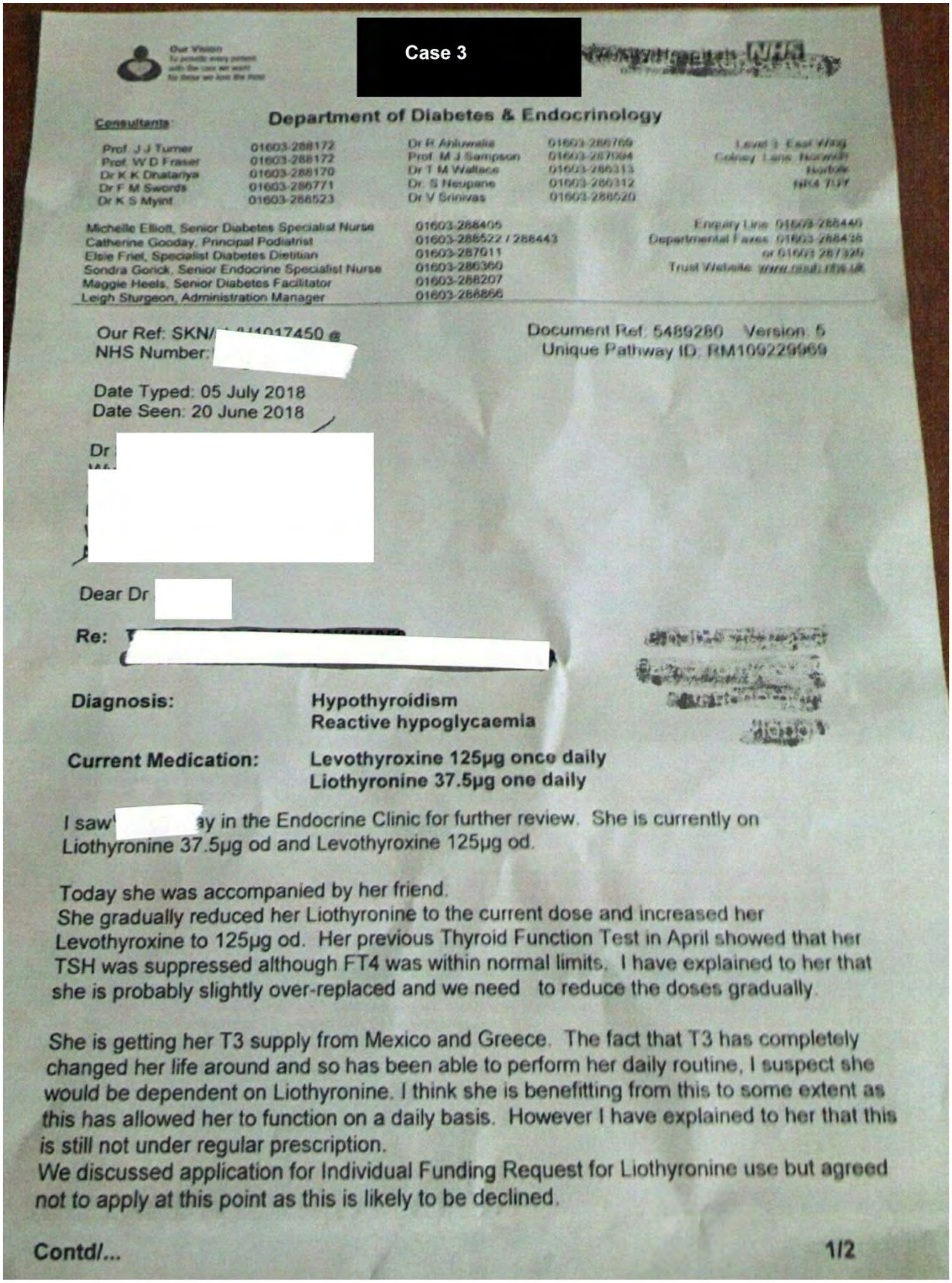
1. Levothyroxine 75µg once daily
2. Liothyronine 37.5µg one daily

It was my pleasure to review this lady in Endocrine Clinic for further review. She remains well in herself and is similar to what she was in the last clinic visit. She is now getting T3 from Mexico and is self-funding. She is aware that we cannot prescribe T3 and has to self-fund. She tells me historically since being on T3 her life has been completely different and is able to function. Prior to that, when she was just on T4, she could not perform a normal daily routine and hence was really limited in many ways. She tells me that there is no way she could come off T3.

Today I discussed if she would be prepared to at least cut back on the dose of Liothyronine. She is happy to try that. I have advised her to increase T4 by 25µg whilst reducing T3.

Dictated and electronically validated by

Dr
Consultant
Diabetes & Endocrinology



Case 3

[redacted]

Department of Diabetes & Endocrinology

Consultants:

Prof J J Turner	01603-288172	Dr R Ahluwalia	01603-286769	Level 3, East Wing
Prof W D Fraser	01603-288172	Prof M J Sampson	01603-287094	Colney Lane, Norwich
Dr K K Dhatariya	01603-288170	Dr T M Wallace	01603-286313	Norfolk
Dr F M Swords	01603-286771	Dr S Neupane	01603-286312	NR4 7UY
Dr K S Myint	01603-288523	Dr V Srinivas	01603-286520	

Michelle Elliott, Senior Diabetes Specialist Nurse	01603-288405
Catherine Gooday, Principal Podiatrist	01603-288522 / 288443
Elsie Friel, Specialist Diabetes Dietitian	01603-287011
Sondra Gorick, Senior Endocrine Specialist Nurse	01603-286360
Maggie Heels, Senior Diabetes Facilitator	01603-288207
Leigh Sturgeon, Administration Manager	01603-288866

Enquiry Line: 01603-288440
Departmental Faxes: 01603-288438
or 01603 287320
Trust Website: www.nnuh.nhs.uk

Our Ref: SKN/[redacted]1017450 @
NHS Number: [redacted]

Document Ref: 5489280 Version: 5
Unique Pathway ID: RM109229969

Date Typed: 05 July 2018
Date Seen: 20 June 2018

Dr [redacted]

Dear Dr [redacted]

Re: [redacted]

[redacted]

Diagnosis:	**Hypothyroidism** **Reactive hypoglycaemia**
Current Medication:	**Levothyroxine 125µg once daily** **Liothyronine 37.5µg one daily**

I saw [redacted]ay in the Endocrine Clinic for further review. She is currently on Liothyronine 37.5µg od and Levothyroxine 125µg od.

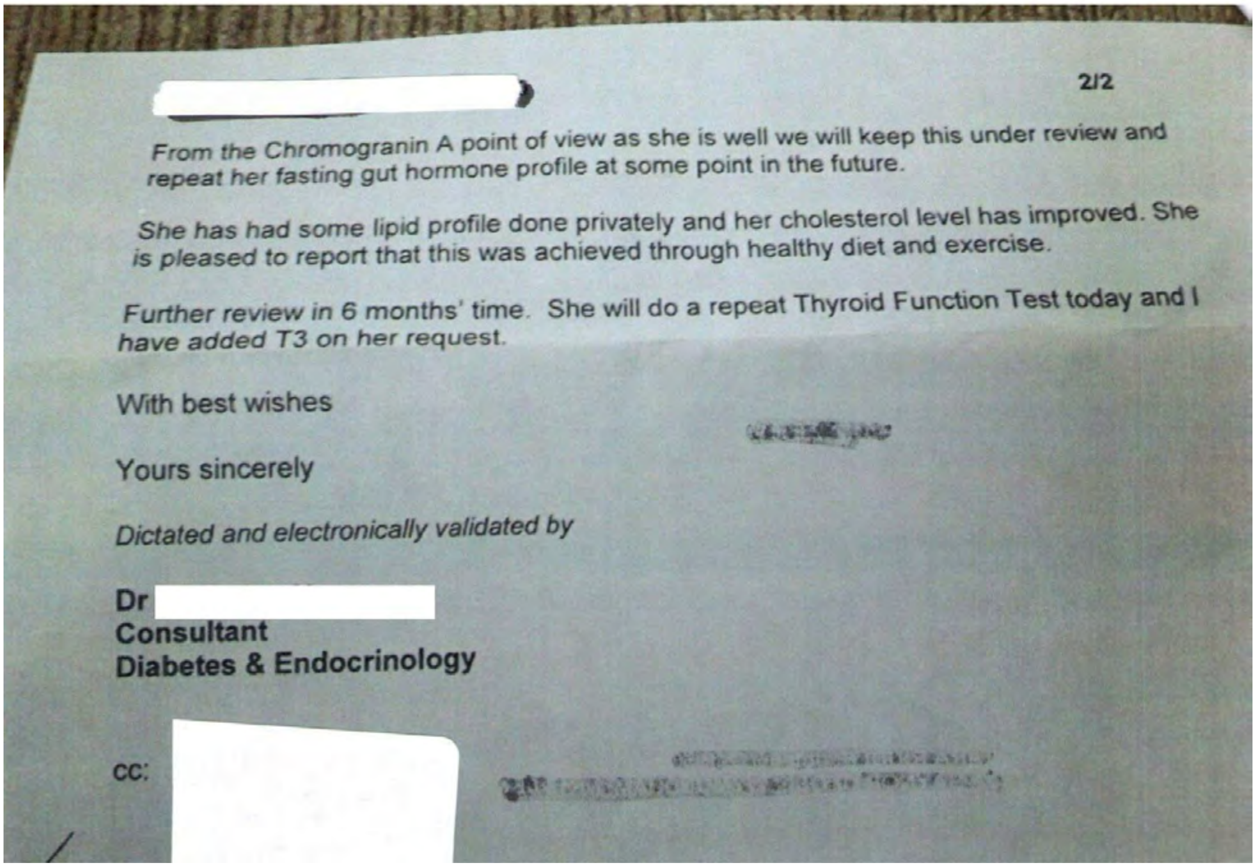
Today she was accompanied by her friend.
She gradually reduced her Liothyronine to the current dose and increased her Levothyroxine to 125µg od. Her previous Thyroid Function Test in April showed that her TSH was suppressed although FT4 was within normal limits. I have explained to her that she is probably slightly over-replaced and we need to reduce the doses gradually.

She is getting her T3 supply from Mexico and Greece. The fact that T3 has completely changed her life around and so has been able to perform her daily routine, I suspect she would be dependent on Liothyronine. I think she is benefitting from this to some extent as this has allowed her to function on a daily basis. However I have explained to her that this is still not under regular prescription.
We discussed application for Individual Funding Request for Liothyronine use but agreed not to apply at this point as this is likely to be declined.

Contd/...

1/2

Case 3



[redacted] 2/2

From the Chromogranin A point of view as she is well we will keep this under review and repeat her fasting gut hormone profile at some point in the future.

She has had some lipid profile done privately and her cholesterol level has improved. She is pleased to report that this was achieved through healthy diet and exercise.

Further review in 6 months' time. She will do a repeat Thyroid Function Test today and I *have added T3 on her request.*

With best wishes

Yours sincerely

Dictated and electronically validated by

Dr [redacted]
Consultant
Diabetes & Endocrinology

cc: [redacted] [redacted]

Case 3

Online access given- as per written request and task from Dr .
Online message from
The practice has granted access to the ... services:
Detailed Coded Record
Summary Record

18 Apr 2016 15:54	Surgery: (Health Professional Access Role)	

Glucoject lancets PLUS 0.2mm/33gauge (A. Menarini Diagnostics Ltd) - 1 pack of 100 la - use directed
GlucoMen areo Sensor testing strips (A. Menarini Diagnostics Ltd) - 2 packs of 50 strip(s) - ted
FP10: Printed On Mon 18 Apr 2016 15:58
Summary Care Record Update

28 Apr 2016 12:14	Surgery: Dr (Clinical Practitioner Access le)	

History: Has been testing blood sugar when symptomatic but all values normal w symptom c - lowest value was 3.8 when symptoms severe but not consistent at other times; next OPA 11/16; will t al of T
Plan: Trial T3 10mcg bd and then up to equivalent which would be 20mcg op T
Liothyronine 20microgram tablets - 1 pack of 28 tablet(s) - half bd
ETP FP10: Printed On Thu 28 Apr 2016 12:29 By Dr
Summary Care Record Update

09 May 2016 12:07	Surgery: Dr (Cl cal oner A R)	

History: Probable benefit; more energy and able to do more tivities; seems m than placebo type effect but ?will it be sustained/improve
Plan: Increase to 1 bd for 2/52- then check bloods and disc s (will need d NA rechecked later)
Liothyronine 20microgram tablets - 1 pack of 28 tablet(s) - bd
ETP FP10: Printed On Mon 09 May 2016 12:15 By Dr
Pathology Request (Complete):
Thyroid profile (Requested)
Summary Care Record Update

10 May 2016 15:13	Surgery: in/Clinical Support Access Role)	

Plan: Referral to hospital phlebotomist (XaKvT)

25 May 2016 09:40	Surgery: Dr Clin ctitioner Access Role)	Entered: 25 May 2016 17:06

Clinical Information: On T3
Thyroid function test (X77Wg)
Serum free T4 level (XaERr) < 5 pmol/L [8 - 21] elow low reference limit
Serum TSH level (XaELV) 0.2 miu/L [0. 5] - B low reference limit
Thyroid function test Report, Abnorm Nee o speak to doctor (Patient Informed)

25 May 2016 16:52	Surgery: Dr (Clinical Practitioner Access Role)	

Has had several really goo days - b han f months; found palps if 20mcg taken in evening but better if spreading dose through day; ha qua has proved - less shedding - and feels entirely different; continue at 20/10/10
Liothyronine 20microgr ets - cks of 28 tablet(s) - 1 bd
ETP FP10: Printed On W May 20 7:00 By Dr
Summary Care Record Update

25 May 2016 17:06	Su Dr al Practitioner Access Role)	
13 Jun 2016	S gery s (Admin/Clinical Support Access Role)	Entered: 28 Jun 2016 10:20

Clinic Letter to Dr n

13 Jun 2016	S rge : Admin/Clinical Support Access Role)	Entered: 28 Jun 2016 10:21
28 Jun 2016	Surg D (Clinical Practitioner Access Role)	

Histo Has sus ned imp vement and feels almost back to normal - able to have normal activities with less fati , still pa self; now taking 20mcg bd; has had radical change in wellbeing
Pla fo can import from EEC- at reduced cost- perhaps try supplementing with T4; have explained that I am prohibi prescribing T3, although will coninue at present
(R) Levoth e sodium 100microgram tablets - 56 - 1 daily
Liothyronine 2 ogram tablets - 2 packs of 28 tablet(s) - 1 bd
ETP FP10: Printed On Tue 28 Jun 2016 11:39 By Dr
ETP FP10: Printed On Tue 28 Jun 2016 11:39 By Dr
Pathology Request (Complete):
Thyroid profile (Requested), *Anti nuclear antibodies (Requested)*
Summary Care Record Update

Medication

A = Acute P = Private I = Instalment Dispensed D = Dental H = Hospital O = Other

Case 4 Story

Patient statement:

I am not sure if my story will be relevant as I live in Scotland and it's my endocrinologist who is not allowed to write me a prescription but here it is…

I was diagnosed with Hypothyroidism in December 2016, I had gone to see my GP with a lump on my neck not thinking that it was connected in any way to how I had been feeling for the last 10 years or so. I was always tired, cold, found it hard to concentrate, very forgetful, had dry skin, my hair was falling out, weight gain, constipation and neck and shoulder pain I told myself that I was working too much or not getting to bed early enough and should get more sleep when in reality I was sleeping 10 -12 hours a day minimum! I had even started nodding off when driving.

The results of the tests came back and I was diagnosed with autoimmune thyroid disease which meant my immune system was destroying my thyroid. I was started on Levothyroxine (L-T4) and I thought OK that explains rather a lot and that I would be eventually back to normal, whatever that was. Dose increase after dose increase followed and although I do not feel quite as bad as I had been I still do not feel well. I wake up in the morning and I don't feel refreshed, I still have shoulder pain - things like drying my hair or even picking up a kettle or hanging out a load of washing hurt. My GP decided to refer me to Ninewells Hospital's endocrinology department for further investigation.

I had my first appointment with my endocrinologist Dr ----- in November 2017. I was rather excited as I thought this would appointment would be life changing I would get to try L-T3 and hopefully live a normal life instead of this half life I lead at the moment. I was very disappointed when the Dr told me that NHS Tayside had put a blanket ban on L-T3 and it was no longer being prescribed due to the soaring cost. He took blood samples and to be quite honest I really did not see the point as he had already said that I could not have L-T3 and I had resolved myself to how I feel at the moment being as good as it gets. He also said that he thought there were other things going on and down the line he would be looking at cognitive therapy, diet and exercise plans, sleep apnea clinic and various other tests. I didn't think very much of him at this point.

On 02/02/18 I went to see Dr ----- for round 2 I was really expecting nothing from him. He asked me how I had been and I said I had been rather unwell at the New Year. I was driving home from work when I started feeling rather strange and the world seemed to be zooming past me and I wasn't able to concentrate very well but I made it home and fell asleep on the sofa and woke up 12 hours later.

Case 4 continued

This episode lasted for a week I had no energy, even making a cup of coffee drained me, I had severe constipation although I had no reason to, was freezing cold even though the heating was set to a tropical 24 and I was sleeping for 12-13 hours a day! He asked me what I wanted. I replied a trial of L-T3 but you have said that is not possible. He said things had changed since he had last seen me and that they were no longer taking patients off L-T3 and he was going to recommend that I should start a trial of L-T3. He said he was unsure of the guidelines regarding new prescriptions but he would find out that day. I was elated I could see a light at the end of this rather dark and long tunnel.

As it turned out Dr ----- was not allowed to write out a prescription for me so then asked my GP if they would fund it, they declined he then said he would apply for it through the hospital but it may take a while as he had a paperwork to complete. I received a letter from in April him saying the panel responsible for making decisions involving requests for non-formulary medications had declined my request as they felt the clinical benefit does not match the cost of the therapy. He has taken this to appeal for me and as yet we have not had any decision from NHS Tayside so it looks as if my appeal has been unsuccessful.

NHS correspondence follows:

Case 4

Tayside NHS Board
Ninewells Hospital and
Medical School
DUNDEE
DD1 9SY
01382 660111
www.nhstayside.scot.nhs.uk

Ms MP

Sent by email: @parliament.uk

Date 14 May 2018
Your Ref KH1698/FW
Our Ref
Enquiries to
Extension
Direct Line
Email

Dear Ms

Thank you for your email of 23 April regarding your concerns relating to the decision making process regarding Liothyronine prescribing in Tayside.

I have sought advice from the Medical Director and Director of Pharmacy to assist in my response to the issues you raise.

It is my understanding that Tayside has a Prescribing Management Programme of work, clinically led through the Prescribing Management Group to address the ongoing challenges of medicines waste, variation and harm. In keeping with a focussed approach to support evidence based, cost effective prescribing the group has identified a number of drugs which may not match these criteria. Proposals to limit or cease prescribing have been discussed through the Area Drug and Therapeutics Committee and its Medicines Advisory Group, the Prescribing Management Group, and NHS Tayside Board.

The approach currently being taken, and endorsed again at the most recent Board meeting to remove Liothyronine from the Tayside formulary is in keeping with Boards across Scotland, and is supported by the letter of November 2017 to all Boards from the national Effective Prescribing Programme and which also takes into account all the recommendations from the 2015 statement by the British Thyroid Executive Committee.

It is of the utmost importance to remember that the thoughts, wishes and opinions of patients and clinicians are taken into account in taking forward these changes, however as an organisation we must be clear that as a whole system we have a fiscal and clinical responsibility to ensure evidence based prescribing.

I hope this response provides the clarity you require however should you have any further queries please do not hesitate to contact me.

Yours sincerely

Chief Executive

Everyone has the best care experience possible
Headquarters: Ninewells Hospital & Medical School,
Dundee, DD1 9SY (for mail) DD2 1UB (for Sat Nav)

Chairman, John Brown CBE
Chief Executive: Malcolm Wright OBE

Case 5 Story

Patient statement:

I attended an appointment with Dr. ----, Basildon Hospital, Thurrock
I was of the understanding that there would be a ‘number’ of endocrinologists there plus a pharmacist. There wasn’t. That meeting took place between themselves.

The doctor would not allow me to record the meeting – said he needed to take legal advice and would refuse the appointment.

A discussion had taken place between them regarding new patients – they would look at individual requests and pre-existing – arguing who should pay, why not primary care?
He said even if was to write the prescription, his pharmacy are refusing to dispense. I asked on what grounds? Chief Executive is saying no prescribing of L-T3 from secondary care.

He is and always has been open to L-T3 therapy. Is now under so much pressure he is considering stopping prescribing altogether. Thinking of not prescribing L-T3 at all.

Is calling a multi-disciplinary with his team as to what is considered ‘well’.

Liaison between primary and secondary care will contact the CCG for clarification on who should prescribe for existing, stabilised patients who cannot be switched to L-T4.

They await clarification of the local guidelines. Until then GP should continue to prescribe

Write to Chief Executive – new one coming in 1st August [name redacted].

I discussed my symptoms when taking L-T4 medication and asked if he felt that was someone living ‘well’. After some dithering, he conceded that living with the symptoms ‘would be difficult’

To be fair, the local guidelines are misleading where prescribing is concerned… They state that:

Prescribers should not accept new requests to prescribe liothyronine or Armour ® Thyroid for hypothyroidism.

Case 5 continued

- *Patients already stabilised on longstanding liothyronine (T3) or Armour ® Thyroid should be switched to an equivalent dose of levothyroxine (L-T4). As per NHSE guidance on 'Items which should not routinely be prescribed in primary care' responsibility for this lies with a consultant Endocrinologist. If GPs wish to switch any patients see table below for switching advice from BTUH.*

- *The Royal College of Physicians considers liothyronine to be a specialist medication which should be prescribed by specialist endocrinologists. In existing patients where switching to an equivalent dose of levothyroxine is not possible or has failed then patients should be referred back to the specialist for continuation of prescribing. The Medicines Management Team recognise that in exceptional cases that prescribing may need to remain in primary care must be considered as an IFR.*

- *Patients taking liothyronine due to intolerance to levothyroxine tablets (e.g. lactose intolerance) should be reviewed and switched to the levothyroxine manufactured by TEVA which is suitable in lactose and galactose intolerance.*

- *Patients who decline to the switch or are intolerant are to be referred to the Endocrinologist.*

NHS correspondence follows:

Case 5

11 June 2018

Ms
Head of Medicines Optimisation
Thurrock CCG
Thurrock Civic Offices
2nd Floor New Road
Grays Essex RM17 6SL

cc. Dr Balfour Medical Centre, 2 Balfour Road, Grays, Essex, RM17 5NS
Dr Basildon & Thurrock University Hospitals NHS Foundation Trust, Basildon University Hospital, Nethermayne, Basildon, Essex, SS16 5NL
Thurrock Labour, @thurrocklabour.org.uk
Thurrock Conservative, mp@parliament.uk
Rt Hon @parliament.uk
Rt Hon
@parliament.uk
(Department of Health and Social Care),
mp@parliament.uk
(Department of Health and Social Care),
.mp@parliament.uk
(Department of Health and Social Care), @parliament.uk

Dear

RE: Continued prescribing of Liothyronine

I write following your letter dated 19th February 2018 to my GP, Dr I have been asked by her to put together a 'case' as to why I should continue to receive Liothyronine prior to re-referral to Dr. at Basildon Hospital, initiating consultant.

__History__

I was diagnosed with an over-active thyroid in late 1996 whilst on holiday in New Zealand, 6 months after the birth of my first child. I was prescribed carbimazole and beta-blockers and continued with these upon my return to the UK. The symptoms subsided after approximately 18 months. At that time, I was never given any information as to the cause of my illness either by the a&e doctors abroad or my GP back in the UK.

In October 2001 I gave birth to my second child. I felt extremely ill immediately after the birth, with shaking and extreme tingling all over my body and facial paralysis. I suffered 4 days of various doctors trying to obtain arterial blood leaving my arms black. I don't believe they ever succeeded. My thyroid illness symptoms returned. Again, I was never actually given a

Case 5

'diagnosis'. This time my thyroid levels could not be regulated. I was prescribed carbimazole and levothyroxine plus beta-blockers and some months later developed thyroid eye disease.

In March 2005 I underwent a total thyroidectomy, having been advised by my doctors it was my only option going forward. Instead, I went backward.

At no time, ever, from initial diagnosis in 1996 have I been given any information regarding my illness. It was never explained that my over active thyroid was a result of Grave's Disease. It was never explained that Grave's Disease is an autoimmune condition and there were possibly various things that I could have tried to reduce antibodies. If I had known then what I know now, I would never have agreed to surgery. Certainly not before trying other remedies. A day after being released from hospital I was rushed back in with hypocalcaemia. Even though this is a classic post-surgery symptom I lay in a&e for 7 hours before being seen. My whole body was tingling and in spasm and I looked like I'd suffered a stroke. 5 days followed where my calcium levels were brought up, only to drop again when staff mistook another patient's blood results for mine. After a promise that, without a thyroid, my illness would be easy to manage with L-T4 monotherapy, I found my quality of life deteriorating year after year. With limited internet access 13 years ago, information of this kind was not readily accessible to a lay person. It was expected that your doctor would explain everything you should know. Sadly, this has never been my experience.

Let me list my symptoms at that time (those that I can remember, because there are many). I have highlighted those that have returned since the reduction in L-T3 from 30cmg to 20mcg along with the re-introduction of L-T4 50mcg:-

- Heart palpitations
- Breathlessness
- Arrhythmia
- Low HR – 55-60bpm
- Weight loss – 9st 12lb to 8st 3lb the first time
- Weight gain – 9st 6lb to 13st 3lb the second time
- Weak muscles
- Joint pain – particularly right knee and ankles
- Extreme fatigue
- Exhaustion after activity
- Cold extremities – feet, hands, nose, buttocks
- Chillblains
- Plantar Fasciitis
- Cognitive – memory, confusion, slurred speech
- Recurrent HSV-2 – the last episode Apr '18 lasting over 3 weeks
- Vaginal thrush
- Shingles
- Excessive sweating
- Heat/cold intolerance
- Disrupted sleep pattern
- Depression
- Anxiety
- Loss of eyebrows
- Food intolerances
- Prolapsed urethra – surgery 2017 – I believe weight gain contributed

L-T4 monotherapy left me feeling like I was slowly dying. Every time I saw my consultant I would talk about these symptoms. Every time only TSH and FT4 were tested. Every time I was sent away with an adjustment to levothyroxine.

I would like to point out the following:-

- As a child I suffered from severe tonsillitis, which continued into adulthood, until their removal at age 26. I was in the doctor's surgery constantly. My family, for a good

Case 5

number of years before my initial diagnosis of thyroid disease, would often ask me what was wrong with my neck. Commenting that it looked swollen and puffy. I had never really taken any notice, as I saw myself in the mirror every day and to me, this is what my neck looked like. I am amazed that, given the amount of time I spent in various surgeries over the years with emphasis on checking my neck (glands), it was never noticed!

- I have suffered from tingling/paralysis over my body since around the age of 14. This concern was brought up to Mr [redacted] prior to my surgery to which I was told it was nothing to worry about. I still suffer from it now. Mr [redacted] was, however, rightly concerned with how good the scar would look!
- I visited the doctor's surgery with a right eye problem prior to thyroid eye disease being diagnosed. My doctor prescribed eye drops. My optician diagnosed the thyroid eye disease.

These are some of the other medications taken by me and investigations undergone during L-T4 monotherapy:-

Amitriptyline – tingling
Fluoxetine - depression
Sertraline – depression
Citalopram - depression
Orlistat – weight maintenance
Reductil – weight maintenance
Aciclovir – HSV-2
Calcium supplementation
Various pain medication

Cardiology – arrhythmias
Rheumatology? - knee pain

In May 2012, 7 years after my surgery and despite my adequate dose of L-T4 monotherapy my TSH remained above range (7.37 mu/L in a range of 0.27-4.2) and my T3 at the lower end of the scale.

Fortunately for me, with the Web very much up and running, I began researching my illness.

I found the information available to be a lifesaver.

I found that numerous symptoms that I had developed over the years could be put down to low thyroid hormone at a cellular level.

I found that there were many reasons why L-T4 monotherapy may not be working for me.

I invested time and money into research and private testing.

I worked on nutrition and supplementation.

I worked on reducing stress, taking up yoga 10 years ago.

And then I found that there was an alternative drug available that had not been offered to me.

After reading a number of books on autoimmune thyroid disease, I went to my consultant armed with information and private lab results to discuss the option L-T4/L-T3 combination therapy. Happily he agreed and I felt a little better but a long way from what I would consider my 'normal' self. After reading Recovering With T3 I returned to my consultant and discussed the option of L-T3 monotherapy. I was curious to see if the removal of T4 would make a difference to the way I felt and was also interested in the method used to restore the circadian rhythm. He agreed we could try. And so I began L-T3 monotherapy at 50mcg. I felt the best I'd felt in years. Most symptoms subsided, some left completely, and my sleep pattern

Case 5

returned to normal within a matter of months. **Yes, my lab work was 'out of range' but I felt well**. I wasn't back to 'normal' but to be honest, I suspect that I'd suffered from this disease from a young teen and so I didn't really know what normal was. This feeling was to be short lived.

Some time, I believe, in 2014 my consultant intimated that he was considering lowering my dose (supposedly based on lab results but more honestly because of cost and certainly not because of any adverse symptoms on my part). I panicked and so agreed to lower the L-T3 dose to 30mcg and introduce a small dose of L-T4, trying combination therapy once more. Symptoms began returning quickly, most immediately weight gain. I took it upon myself to stop the L-T4 and continued on L-T3 only at 30mcg. I kept an eye on my symptoms and checked my heart rate and blood pressure regularly. When I returned for, what was to be my last, appointment with my consultant, I was hoping that he would support my return to L-T3 monotherapy and that my dose would be reinstated. I found on that day that the ultimate aim was to deny me of the drug entirely. On that day I requested a discharge from the service. I could not see the point of two appointments per year that did nothing for me. It was a waste of both of our time.

Since then my GP has continued to prescribe L-T3 at 30mcg and I had felt relatively well with only a gain in weight, some palpitations and arrhythmia and poor temperature control.

In November 2017 my GP relayed to me that the CCG had advised withdrawing L-T3 from patients. I again agreed to reintroduce L-T4 and reduced my L-T3 to 20mcg in anticipation of a complete withdrawal. My symptoms returned like a lighting bolt and I have felt terrible since, although not as incapacitated as when I was on L-T4 monotherapy. I then found in early 2018 that my GP had received a letter from the CCG advising all patients on L-T3 to be referred back to their original consultant for continued prescribing. I now find myself in the position of having to put a 'case' together to beg for my medication and find myself thinking that it would have been really nice if, for once, I had a medical professional fighting on my behalf.

The Case

Your letter makes reference to the NHSE consultation. If the consultation you refer to is this one: **Items which should not routinely be prescribed in primary care: A Consultation on guidance for CCGs**, it clearly makes reference to liothyronine not being initiated in primary care. ***I am not a new patient. I have received L-T3 for 6 years, 5 of those L-T3 monotherapy, and I am (was) stable***. It also states that a clinical need for liothyronine to be prescribed in primary care be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional. ***If that clinical need is demonstrated, which I believe it has been, I see no reason for my medication not to be prescribed by primary care.***

At the time of my last consultant appointment, I understand liothyronine had been placed on a "DROP list". I looked up said list. It stated one of the reasons for inclusion being:

- For primary hypothyroidism, UK and international guidelines have found no consistently strong evidence for the superiority of alternative preparations (L-T4 + L-T3 combination therapy or thyroid extract therapy – preparations containing dried animal thyroid extracts, such as Armour Thyroid) over monotherapy with levothyroxine in improving health outcomes.

There may be little research into the effectiveness of L-T3 therapy but that doesn't mean it doesn't work. I would suggest you speak to the numerous patients who have found this drug to significantly improve their quality of life. THAT should be evidence enough.

The List also stated an indicative annual saving of £7 million based on a 50% reduction in prescribing. I would argue that once you have to start treating patients for the numerous symptoms that come with being under medicated, the NHS will pay out just as much. Please consider the amount of medication I was once taking, plus investigations. = false economy.

In recent years T3 (liothyronine) has been subject to a 6,000% increase in the cost of the drug by the manufacturer Concordia, who were subsequently referred to the Competition and Markets Authority (CMA) by the Department of Health. In November 2017 the CMA provisionally found that Concordia, the monopoly supplier, abused its dominant position to overcharge the NHS by many millions of pounds for their product, liothyronine. According to the CMA, the amount the NHS paid increased from about £4.46 per pack before de-branding in 2007 to £258.19 by July 2017 while production costs remained broadly stable.

The NHS pays approximately £9 for a liothyronine tablet. In 2007 the cost of a liothyronine tablet was 16 pence or £15.92 for 100 tablets, an increase of almost 6,000%.

Procurement of liothyronine is not being well-managed by the by the various NHS bodies responsible as the cost of this medication in Europe is 25p per tablet compared with £9 in the UK.[SEP] The NHS has not taken measures to manage cost by importing liothyronine from the EU where similar standards are required at a fraction of the cost. The MHRA who are responsible for medicine licencing for the UK describes liothyronine as "*... a well established, bio- identical and already approved drug manufactured across Europe*". It raises the question about why the cost of liothyronine in the UK is significantly higher than in Europe.

T3 in itself is not a costly drug. It is a vital hormone, the cost of which has been artificially inflated for profit. By withdrawing liothyronine you will leave me with no option but to self medicate from unreliable sources (an option given to me by my consultant). **Doctors have a legal duty of care. Anything less is negligent.**

Whilst I am sympathetic and understand the need for the NHS to prevent unnecessary costs at this time, it should not come at the expense of patients who are proven to not respond to certain therapies.

I would direct you to the following:-

1. General Medical Council – Good Medical Practice – "The duties of a doctor registered with the General Medical Council." – ethical guidelines state:-

- "...you **must** show respect for human life..."
- "you **must** make the care of your patient your first concern."
- "Take prompt action if you think that patient safety, dignity or comfort is being compromised."
- "Protect and promote the health of patients..."
- "Listen to, and respond to, their concerns and preferences."

2. BTA – December 2016 - http://www.british-thyroid-association.org/sandbox/bta2016/information_for_endocrinologists.pdf

Although the BTA's stance remains that L-T4 therapy is an effective treatment for a **"majority"** of patients, it also recognises that "a proportion of patients on L-T4 continue to suffer with symptoms despite adequate biochemical correction *[although patients on T3 will have suppressed TSH]* and that a carefully audited trial of L-T3 under the supervision of an accredited endocrinologist might be warranted in exceptional cases."

The BTA also states its concern that requests by local health authorities to withdraw L-T3 therapy from patients is driven by cost and not clinical need and **"that the BTA position statement on the management of hypothyroidism is being inappropriately cited to support this requests."!**

Case 5

"We wish to emphasise that the decision to continue or stop L-T3 should be based on clinical need above other considerations and that the BTA position statement should in no way be used as an endorsement for discontinuing L-T3."

The BTA's clinical approach to patients on L-T3 states **"For patients who are established on L-T3 and are considered to be stable, a change to L-T4 monotherapy should not be implemented without discussion with the patient. In such cases change of treatment may result in significant instability of thyroid status and potentially undesirable clinical outcomes, which may prove more costly than continuation with L-T3 therapy."** = false economy (see medications and investigations when on L-T4 monotherapy).

3. NHS document **"ITEMS WHICH SHOULD NOT BE ROUTINELY PRESCRIBED IN PRIMARY CARE"**

The document lists liothyronine under the category of **"Items which are clinically effective but where more cost-effective items are available in most cases (this includes items that have been subject to excessive price inflation):"** I would argue that "clinically effective" refutes claims that L-T3 therapy is non-effective and withdrawal over the past few years is purely down to cost. But "undesirable clinical outcomes" [BTA] would result in L-T4 monotherapy not being a "more cost-effective" item.

Pages 19-20 states "Advise CCGs that a local decision, involving the Area Prescribing Committee (or equivalent) informed by National guidance (e.g. from NICE or the Regional Medicines Optimisation Committee), should be made regarding arrangements for on-going prescribing of liothyronine. This should be for individuals who, in exceptional circumstances, have an on-going need for liothyronine as confirmed by a consultant NHS endocrinologist." **I believe my need has been established by a consultant NHS endocrinologist**

4. Please see attached "Safety review of liothyronine use: a 20 year observational follow up study"

I no longer drink alcohol. I no longer smoke (although I was never a heavy smoker). I track my calorie intake using an online tracker. I am aware of the calories in versus calories out rule. I am a qualified PT and a yoga teacher in training. I am active, save for when fatigue, exhaustion and palpitations intervene. My weight is not related to my lifestyle or being uneducated. It is due to my illness and being under-medicated. Though this may be seen as purely aesthetic I am sure you will agree being overweight brings a myriad of other health problems.

So to summarise:-

- My quality of life on L-T4 monotherapy is very poor as per the symptoms listed above.
- My t3 level on L-T4 monotherapy is low, warranting a clinical need for L-T3.

Why am I so concerned with my quality of life?

- I have just turned 50. I have been dealing with this illness for at least 22 years, most likely a lot longer. The illness can be debilitating.
- I need to work. Something I cannot do when I am under-medicated and dealing with the myriad of symptoms from this illness.
- By far, the biggest reason of all, is being the mother to a child who is diagnosed with an unrecognised genetic disorder (inherited from me). At 16, he has moderate to severe learning difficulties and will never live independently. He has an older brother but apart from that, I have no siblings. My parents are now in their 70s and can only offer so much help. I have spent years in and out of hospital with my son whilst dealing with my own illness. He is diagnosed epileptic. He has undergone a right nephrectomy. He is hearing impaired. He has limited speech. I have theoretically

Case 5

[redacted]

looked after a 3 year old for 13 years and in all probability little will change in the future. He requires an adult to be with him at all times. I have to keep healthy.

From November 2017 to 1st June 2018 my treatment has been L-T4 50mcg/L-T3 20mcg combination therapy. The level of exhaustion I have felt over the last couple of months has had a dramatic effect on my quality of life. It has brought with it returning feelings of depression, no enthusiasm, no light at the end of the tunnel and feelings of being totally overwhelmed. (Indeed, I picked my two dogs up and took them to kennels a week ago for rehoming because I just could not cope with the fatigue and tiredness and they were an extra burden. We returned 4 days later to bring them home where the member of staff herself commented on how completely overwhelmed I had been). I now have another HSV-2 outbreak for which I will visit the GP today. I have made the decision to (again) drop LT-4 and return to LT-3 monotherapy at 30mcg (as that is my current allowance). If I am forced to, I will self-medicate which puts me in an unsafe, vulnerable position. I will then have no option but to report my GP to the GMC as they have a contract with me, the patient, and not the CCG.

I await the appointment to see Mr , consultant endocrinologist and original prescribing consultant. In the meantime, I wonder if you would clarify the position regarding budgets as there currently seems to be a butting of heads between CCGs and consultants as to who should pay for treatment?

I respectfully ask you to carefully consider everything I have had to say and, in doing so, come to a decision of allowing me to continue to receive L-T3 monotherapy. I believe I have demonstrated a clinical need.

Yours truly,

Encs:

Safety review of liothyronine use: a 20 year observational follow up study

Case 9 Story

Patient statement:

After 40 yrs of being prescribed L-T4, and additionally L-T3 for the last 9 of those years, last August 2017, within a couple of weeks of each other, my GP reduced my L-T4 by almost half and summarily withdrew my L-T3 completely, allegedly at the instruction of the CCG. Despite this catastrophic change to my long-term medication, my GP has not subsequently tested my FT3 to monitor the effect of withdrawing my L-T3, and has tested my TSH only once. Despite having limited resources and having been forced to retire due to my decline in health, I paid to have a private blood test carried out in January 2018, the results being:

TSH 2.46 (0.27 - 4.3)
FT4 14.5 (12.0 - 23.0)
FT3 3.2 (3.1 - 6.8)

As you can see, the FT3 is almost out of range and clearly too low to support healthy functioning. I plan to have a further test to track any changes over time as I had now been without my L-T3 / on the low dose of L-T4 for a considerable time. However, my weight has increased quite literally day by day, and I've gone from a healthy size 12 to a very unhealthy size 22 - at only 5' 1" and with a heart condition, kyphoscoliosis, and full length spinal deterioration, this is devastating.

I also had a DIO2 (T92A) re225014 gene test carried out by Regenerus, the results being Homozygous variant genotype AA, the consequence of which is ‘a decreased ability of the enzyme to generate the active L-T3 hormone, and is associated with insulin resistance and obesity.’

My new Endocrinologist said, in response to my story, ‘I'm not surprised you feel ill’ and offered to recommend reinstatement of L-T3 to my GP, and to manage my care with a view, amazingly, to increasing my previous dose of 20mcg to 40mcg. A copy of his January letter to my GP is attached (see doc ST3.1). The response from my GP and/or CCG? A deafening silence. A second GP agreed in March to write to the CCG - I've met with silence since then too. Meanwhile my health continues to deteriorate.

In March my MP also wrote to the CCG on my behalf, but again, no response whatsoever. I am simply being ignored, after a lifetime of paying in to the NHS - whilst my overall health deteriorates and the resultant demand on a wide range of NHS services ensues.

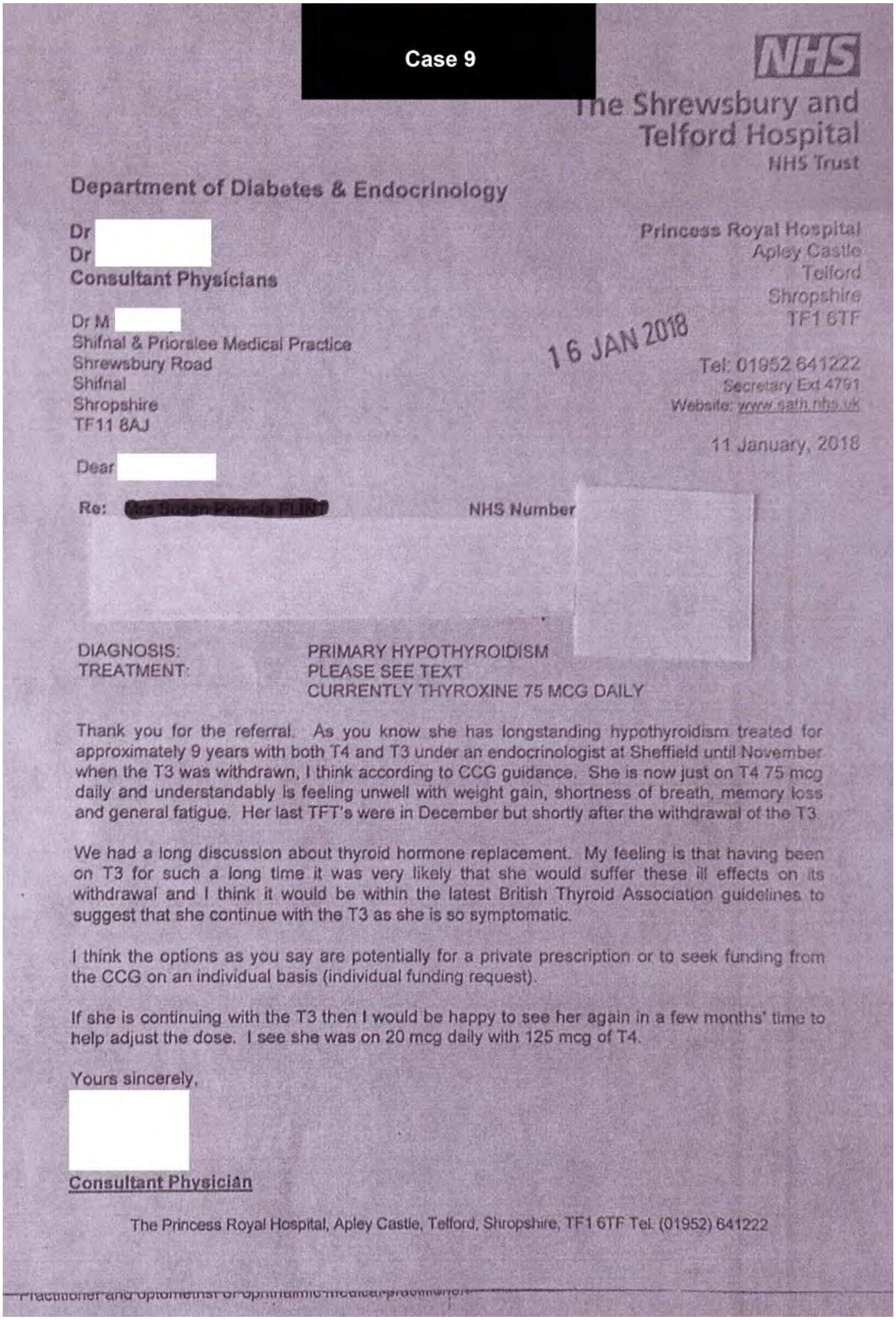
Case 9 continued

I now feel desperately unwell, fatigued, breathless etc. with considerable associated hair loss and dental deterioration, and with very poor cognitive and memory functions.

I desperately hope the very immediate specific problem of L-T3 prescribing can be quickly overturned.

See Document referred to by Shropshire CCG re: L-T3[12].

NHS correspondence follows:



Case 9

NHS
The Shrewsbury and
Telford Hospital
NHS Trust

Department of Diabetes & Endocrinology

Dr [redacted]
Dr [redacted]
Consultant Physicians

Princess Royal Hospital
Apley Castle
Telford
Shropshire
TF1 6TF

Tel: 01952 641222
Secretary Ext 4791
Website: www.sath.nhs.uk

Dr M [redacted]
Shifnal & Priorslee Medical Practice
Shrewsbury Road
Shifnal
Shropshire
TF11 8AJ

16 JAN 2018

11 January, 2018

Dear [redacted]

Re: [redacted] **NHS Number** [redacted]

[redacted]

DIAGNOSIS: PRIMARY HYPOTHYROIDISM
TREATMENT: PLEASE SEE TEXT
CURRENTLY THYROXINE 75 MCG DAILY

Thank you for the referral. As you know she has longstanding hypothyroidism treated for approximately 9 years with both T4 and T3 under an endocrinologist at Sheffield until November when the T3 was withdrawn, I think according to CCG guidance. She is now just on T4 75 mcg daily and understandably is feeling unwell with weight gain, shortness of breath, memory loss and general fatigue. Her last TFT's were in December but shortly after the withdrawal of the T3.

We had a long discussion about thyroid hormone replacement. My feeling is that having been on T3 for such a long time it was very likely that she would suffer these ill effects on its withdrawal and I think it would be within the latest British Thyroid Association guidelines to suggest that she continue with the T3 as she is so symptomatic.

I think the options as you say are potentially for a private prescription or to seek funding from the CCG on an individual basis (individual funding request).

If she is continuing with the T3 then I would be happy to see her again in a few months' time to help adjust the dose. I see she was on 20 mcg daily with 125 mcg of T4.

Yours sincerely,

[redacted]

Consultant Physician

Practitioner and optometrist or ophthalmic medical practitioner

Case 10 Story

Patient statement:

I'm 47 female with Hashimoto’s thyroid disease. I was borderline for a long time and finally diagnosed about 15 years ago after my second child. I struggled to get pregnant and ended up on the fertility drug, Clomid.

After my second child I was feeling awful and was told that I had hypothyroidism take this pill and that's it. For a few years L-T4 seemed to work OK; I struggled with weight gain but otherwise I managed.

As the years passed I felt half the woman I was, brain fog, fatigue, low blood pressure, joint pain. The list went on and on. Eventually I was struggling to get out of bed, or look after my children let alone myself. My weight crept up, I felt awful constantly.

My L-T4 was raised and I was sent away. I begged my GP for help. Eventually I started doing my own research, I read about NDT the good and the bad and also L-T3.

When I was referred to an endocrinologist I asked about help. I was told my TSH was fine and that the other stuff was quackery. I came away and continued to decline in health another endocrinologist appointment diagnosing chronic fatigue syndrome.

Still ill, I continued to visit my GP, along came raised liver enzymes, b12 deficiency, folate deficiency, fatty liver disease, high blood pressure, hair loss, severe hot/cold intolerance, head sweats, palpitations, dizziness, fibromyalgia, the list was endless.

Eventually my feet and ankles started swelling and I had 15 back to back infections. I took antibiotics for water infections, chest Infections, skin infections. You name it I caught it.

I had stomach problems and had 3 attempts at h-pylori treatment, my joints were unbearable so I had private blood tests.

It showed I had high antibodies and a very poor T4 to T3 ratio and it was suggested I wasn't converting very well. I honestly thought I was dying and so did my husband.

I researched an endocrinologist who didn't specialise in diabetes and asked for a new referral. I was given a trial of L-T3 and my life changed!

Case 10 continued

I have energy, my palpitations, high blood pressure, liver enzymes, head sweats, cold /heat intolerance etc have gone completely. I have had not a single infection, my joints pain is more manageable my skin in no longer flaky and dry. There are so many important improvements.

I can function again, the years of poor treatment have left their mark on me. I have B12 injections every 8 weeks and now see a rheumatologist and I have a life.

I will be forever grateful for my L-T3 but live in fear that I will have it removed at anytime due to the cost and funding issues.

Thank you for looking into this issue and to listening to the thousands like me for whom L-T4 is not working for and we are left fighting for our lives dying a slow uneventful death.

L-T3 saved me. That's the long and short of it.

Thanks for listening.

Case 11 Story

Patient statement:

I was diagnosed with under active thyroid 6 years ago, at the age of 31. I'd years of feeling off, tired, bad immune system, I'd constantly have tonsillitis. Every time I went to the doctor I was told I had low iron - even though I took iron tablets.

Anyway, finally after being threatened with losing my job, due to my sick record, a locum doctor at my surgery decided he would take a full blood count (it took 4 years to get a full blood count even though I had many of the underactive thyroid symptoms).

Taking L-T4, never made me feel any different even though I was told I was now well. So all my tiredness and rundown was clearly my lifestyle and stress. I was very active- competing in an Ironman just before I started L-T4 , yet my weight was going up!

I continued to struggle to train. Still my doc said all was fine. I got married and we were trying for children, with no luck, my doc put us forward for IVF. We went through this process, miscarrying. At no point did anyone point to my thyroid.

I eventually fell pregnant and had the most awful pregnancy. Struggling to function. I was signed off work for the entire pregnancy. I was always told my thyroid was fine - even though having since seeing my test results my thyroid was not fine. It was in the gutter - but the magical TSH was low. So no further treatment was proposed.

After that I started getting heart problems. This was investigated and put down to stress!! Ectopic beats - we won't do anything as your resting heart rate is low (45). I went to see a specialist thyroid doctor- best thing I ever done. I went to see Dr ----. Who agreed that I was very undermedicated and wrote to my GP to have my L-T4 increased as this would increase my L-T3. I felt slightly better, but I still want right. Dr ---- agreed to write again to my doctor to prescribe L-T3. My doctor and the NHS endo refused, clearly stating price as the main reason. Also, they refuse to test L-T3 in our region, so definitely no.

I now source my L-T3 from abroad - for £50 per year.

6 weeks after starting L-T3 (after another miscarriage) I was pregnant. Coincidence? I doubt it. I went on to have a successful pregnancy, which was much easier than the last.

Case 11 continued

You need to get this situation sorted. Thousands - of mainly women - are in the same position as me. I’m back at work, rarely sick, and my life is nearly normal. I couldn’t function without this drug. I should be able to access it on the NHS. Having it saves the country money as I’m able to work and not be on benefits. I work in a high pressure active job and have done for 20 years. I serve my country and I feel let down by the NHS’s policies and my MP should be standing up for me.

Case 12 Story

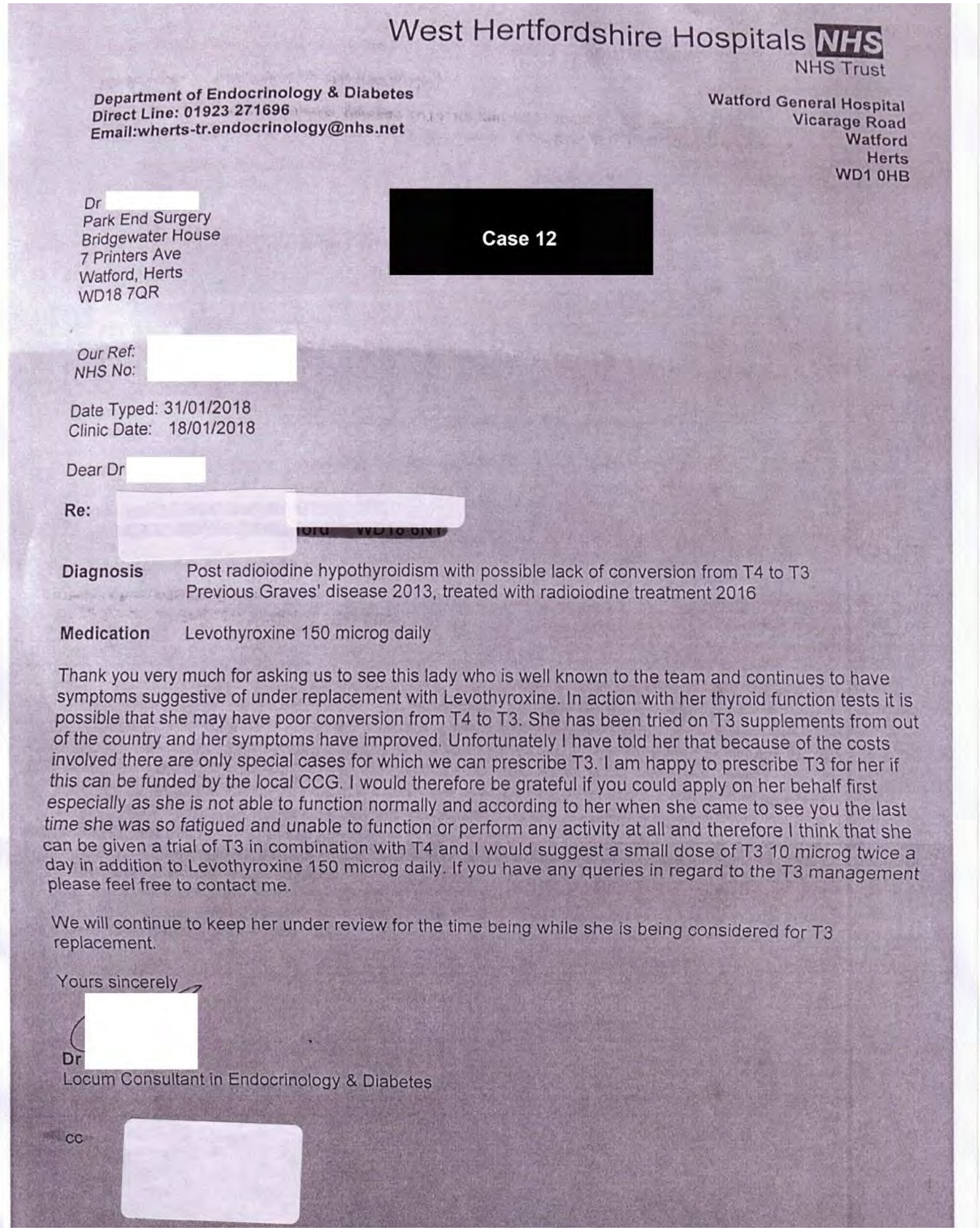
Patient statement:

“I was finally told by my endocrinologist in January 2018 that I would benefit from L-T3, however he referred me back to my GP for a prescription. My GP requested funding as advised by the endocrinologist but this funding was refused.

Please see attached letters for confirmation of these facts.

My GP and my endocrinologist both agree I need L-T3 but nobody will give me a prescription, meanwhile I am too ill to work or effectively care for my autistic child as my doctors have both informed me that I have poor conversion of L-T4 to L-T3, due to this my body can not function properly.”

NHS correspondence follows:



West Hertfordshire Hospitals **NHS**
NHS Trust

Department of Endocrinology & Diabetes
Direct Line: 01923 271696
Email:wherts-tr.endocrinology@nhs.net

Watford General Hospital
Vicarage Road
Watford
Herts
WD1 0HB

Dr [redacted]
Park End Surgery
Bridgewater House
7 Printers Ave
Watford, Herts
WD18 7QR

Case 12

Our Ref: [redacted]
NHS No:

Date Typed: 31/01/2018
Clinic Date: 18/01/2018

Dear Dr [redacted]

Re: [redacted]

Diagnosis	Post radioiodine hypothyroidism with possible lack of conversion from T4 to T3 Previous Graves' disease 2013, treated with radioiodine treatment 2016
Medication	Levothyroxine 150 microg daily

Thank you very much for asking us to see this lady who is well known to the team and continues to have symptoms suggestive of under replacement with Levothyroxine. In action with her thyroid function tests it is possible that she may have poor conversion from T4 to T3. She has been tried on T3 supplements from out of the country and her symptoms have improved. Unfortunately I have told her that because of the costs involved there are only special cases for which we can prescribe T3. I am happy to prescribe T3 for her if this can be funded by the local CCG. I would therefore be grateful if you could apply on her behalf first especially as she is not able to function normally and according to her when she came to see you the last time she was so fatigued and unable to function or perform any activity at all and therefore I think that she can be given a trial of T3 in combination with T4 and I would suggest a small dose of T3 10 microg twice a day in addition to Levothyroxine 150 microg daily. If you have any queries in regard to the T3 management please feel free to contact me.

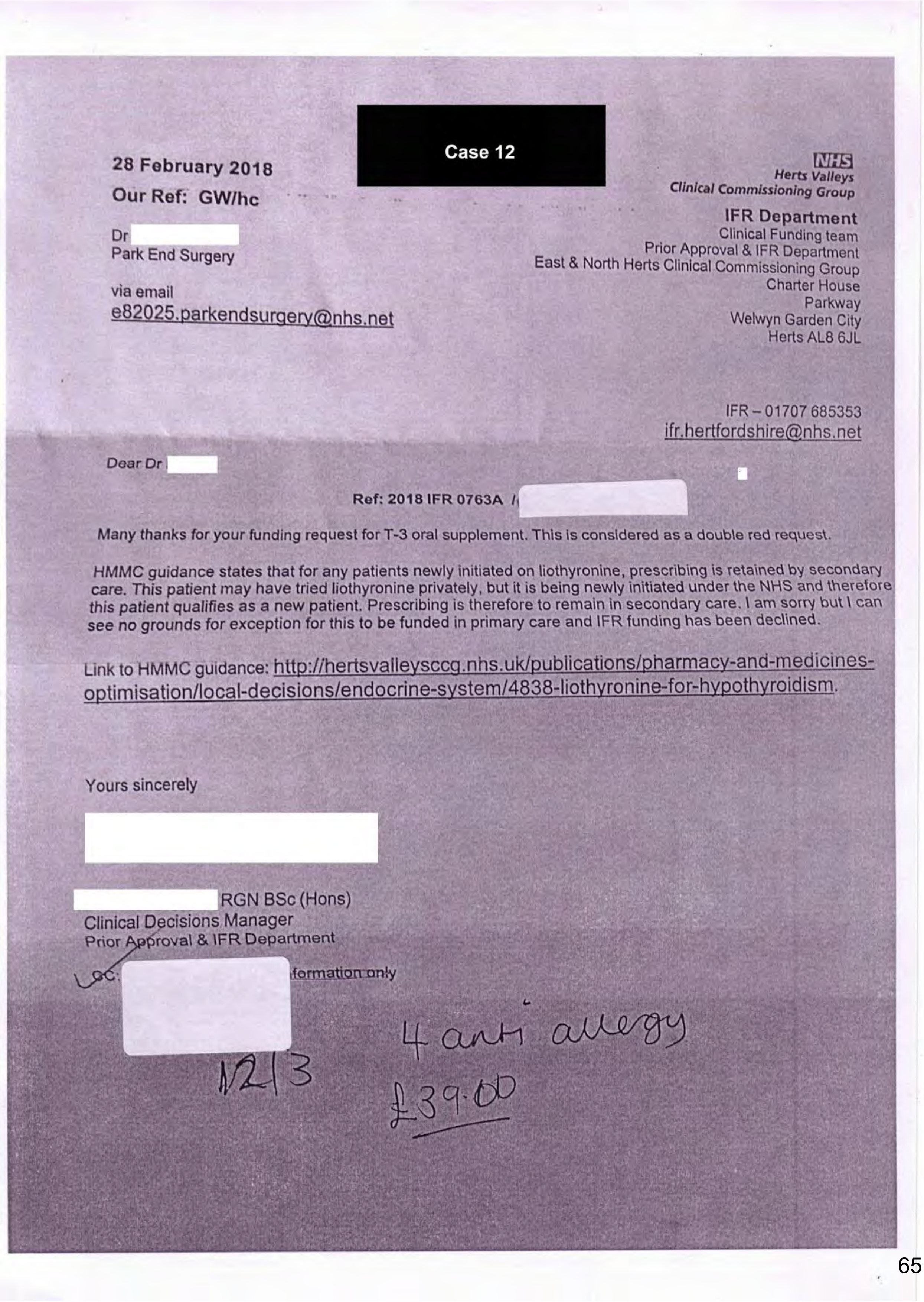
We will continue to keep her under review for the time being while she is being considered for T3 replacement.

Yours sincerely

[redacted]

Dr
Locum Consultant in Endocrinology & Diabetes

cc [redacted]



Case 12

28 February 2018

Our Ref: GW/hc

NHS
Herts Valleys
Clinical Commissioning Group

IFR Department
Clinical Funding team
Prior Approval & IFR Department
East & North Herts Clinical Commissioning Group
Charter House
Parkway
Welwyn Garden City
Herts AL8 6JL

IFR – 01707 685353
ifr.hertfordshire@nhs.net

Dr [redacted]
Park End Surgery

via email
e82025.parkendsurgery@nhs.net

Dear Dr [redacted]

Ref: 2018 IFR 0763A / [redacted]

Many thanks for your funding request for T-3 oral supplement. This is considered as a double red request.

HMMC guidance states that for any patients newly initiated on liothyronine, prescribing is retained by secondary care. This patient may have tried liothyronine privately, but it is being newly initiated under the NHS and therefore this patient qualifies as a new patient. Prescribing is therefore to remain in secondary care. I am sorry but I can see no grounds for exception for this to be funded in primary care and IFR funding has been declined.

Link to HMMC guidance: http://hertsvalleysccg.nhs.uk/publications/pharmacy-and-medicines-optimisation/local-decisions/endocrine-system/4838-liothyronine-for-hypothyroidism.

Yours sincerely

[redacted]

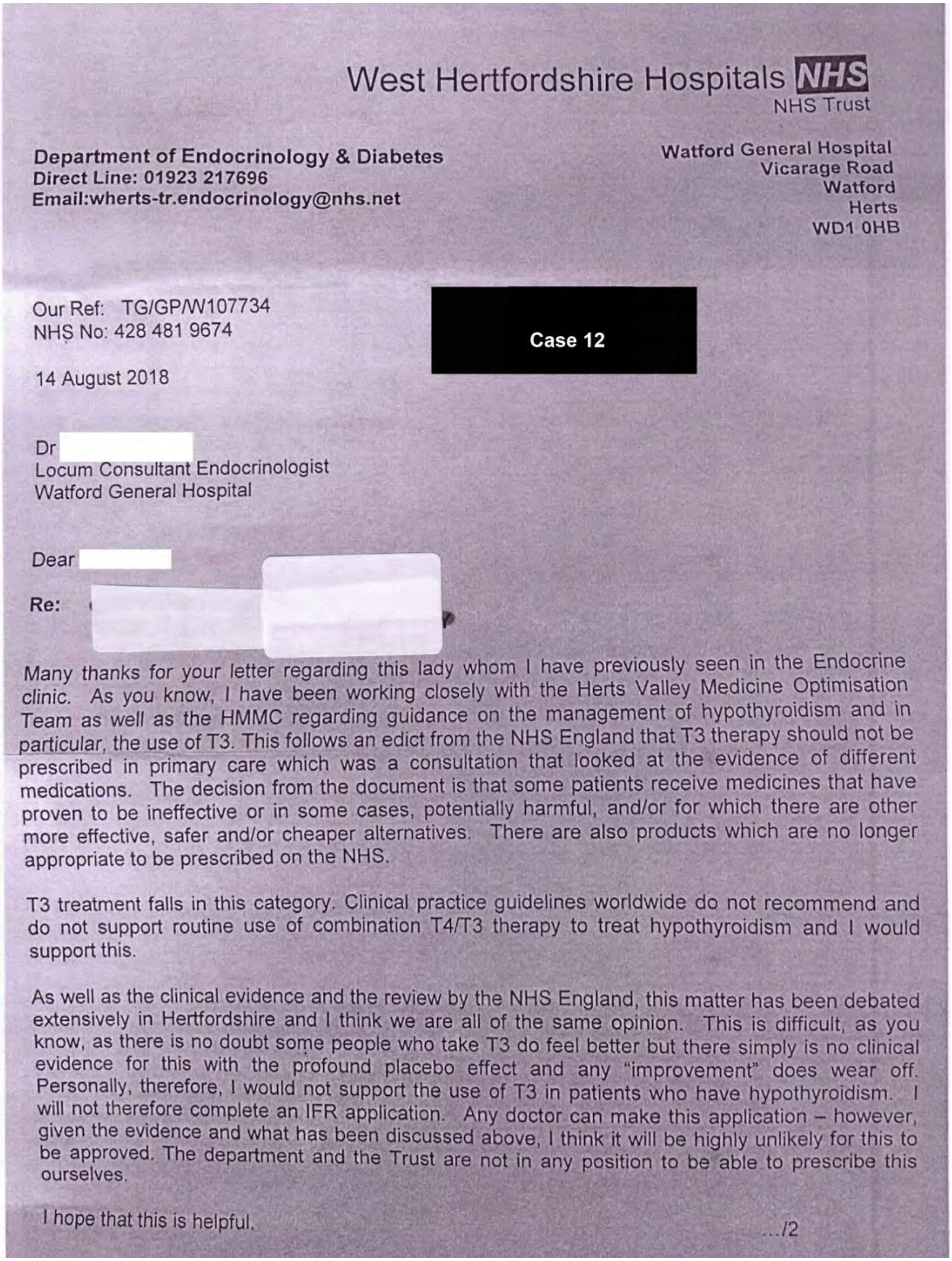
[redacted] RGN BSc (Hons)
Clinical Decisions Manager
Prior Approval & IFR Department

cc: [redacted] formation only

4 anti allergy

12/3

£39.00



West Hertfordshire Hospitals NHS
NHS Trust

Department of Endocrinology & Diabetes
Direct Line: 01923 217696
Email:wherts-tr.endocrinology@nhs.net

Watford General Hospital
Vicarage Road
Watford
Herts
WD1 0HB

Our Ref: TG/GP/W107734
NHS No: 428 481 9674

Case 12

14 August 2018

Dr [redacted]
Locum Consultant Endocrinologist
Watford General Hospital

Dear [redacted]

Re: [redacted]

Many thanks for your letter regarding this lady whom I have previously seen in the Endocrine clinic. As you know, I have been working closely with the Herts Valley Medicine Optimisation Team as well as the HMMC regarding guidance on the management of hypothyroidism and in particular, the use of T3. This follows an edict from the NHS England that T3 therapy should not be prescribed in primary care which was a consultation that looked at the evidence of different medications. The decision from the document is that some patients receive medicines that have proven to be ineffective or in some cases, potentially harmful, and/or for which there are other more effective, safer and/or cheaper alternatives. There are also products which are no longer appropriate to be prescribed on the NHS.

T3 treatment falls in this category. Clinical practice guidelines worldwide do not recommend and do not support routine use of combination T4/T3 therapy to treat hypothyroidism and I would support this.

As well as the clinical evidence and the review by the NHS England, this matter has been debated extensively in Hertfordshire and I think we are all of the same opinion. This is difficult, as you know, as there is no doubt some people who take T3 do feel better but there simply is no clinical evidence for this with the profound placebo effect and any "improvement" does wear off. Personally, therefore, I would not support the use of T3 in patients who have hypothyroidism. I will not therefore complete an IFR application. Any doctor can make this application – however, given the evidence and what has been discussed above, I think it will be highly unlikely for this to be approved. The department and the Trust are not in any position to be able to prescribe this ourselves.

I hope that this is helpful.

.../2

Case 18 Story

Patient statement:

Here is my thyroid story. I was diagnosed initially in 2007 as sub-clinical hypothyroid following a visit to the GP. After a year, I was tested again and my TSH was 2.9 (0.3- 4.2) and my L-T4 was 10.3 (12-22) and therefore below range. L-T3 was not tested. I had a myriad of symptoms including Depression/low mood and high cholesterol.

I was told I had become hypothyroid and put on a low dose of L-T4 (25mcg). This was increased over time to 50mcg, then by summer 2014, I was on 100mcg mainly because I felt no better, not because of the TSH or L-T4 levels. The GP kept wanting to reduce my dose and eventually insisted I reduce the dose of L-T4 to 75mcg/100mcg.

By that winter I was feeling very depressed and low. By Feb 2015, I had realised that despite taking L-T4, none of my symptoms had changed. In fact symptoms had worsened. I saw the GP who told me that my TSH was too low. My TSH was 0.11 (0.3-4.2). I told my GP that I didn't feel well on my current meds and was still suffering with many symptoms.

I began to realise that it was not unusual to continue to feel unwell on L-T4 alone and that I couldn't go on feeling as I did. I felt as though I was living a half-life.

In desperation, I went to see my Pharmacist, who told me that I could safely increase my L-T4 and that if I felt better after 2 weeks, she would write to the GP and ask for a medicine review. I increased the L-T4 slightly to 100mcg and 75mcg alternate days. I went back to the Pharmacist after 2 weeks and told her that I had immediately felt better. On the downside, though my head felt strange, a bit like a muzzy hangover feeling and I had slight palpitations.

In September 2015, I had blood tests which showed my TSH as 0.45 (0.3-4.2) and L-T4 as 20.4 (12-22) and L-T3 3.9 (3.1-6.8). I had heard about L-T3 and that it helped some hypothyroid sufferers to feel better and I began to wonder if this would help me. I wondered if I had a faulty gene DIO2 where the conversion from L-T4 to L-T3 is less efficient. I arranged for a private test and this confirmed that I had a the polymorphism DIO2.

I asked my GP to refer me to an Endocrinologist. In the meantime, I bought some L-T3 online from a recommended supplier and topped this up on a subsequent visit to Greece. Before taking any, I recorded my blood pressure, pulse, basal temperature and weight while on 100/75mcg L-T4 daily up to 1st April 16. By this time I noted additional symptoms including insomnia, even drier skin and fragile nails, and weird cramps.

Case 18 continued

In April 2016, I started to take 75 mcg L-T4 daily and kept records of any change in symptoms. In May 2016 I added 6.25mcg L-T3 by splitting the 25mcg tablet into 4 and continued to record my clinical data blood pressure, etc. I gradually increased my L-T3 dose until I was on 18.75mcg L-T3 and 50mcg L-T4 daily.

When I finally got to see the Endocrinologist in Dec 2016, I took all my clinical records with me and showed him the slowly increasing doses of L-T3 that I had taken.

The Endocrinologist recommended a change of dose to 25mcg x L-T3 daily + 50mcg L-T4. He agreed to oversee me on L-T3, provided I source it myself. I was over the moon that he was going to oversee me on my treatment plan as I had never wanted to self-medicate, but felt I had no choice, but less than delighted that I was expected to source the medicine myself. I told him that I had experienced a significant improvement in my symptoms.

He subsequently wrote to me in March 17, effectively making a complete U-turn. He noted that while I had a number of symptoms that suggested 'under' replacement, he suggested that my 'hypothyroid symptoms' may not fully resolve no matter what combination of thyroid hormone I may take. He suggested that my blood tests showed 'over replacement'. My Feb 17 results that he based this letter on, were TSH 0.01 (0.27-4.20), Free T4 9.15 (12-22) and T3 6.5 (3.1-6.8). Nothing in my other clinical measures indicated that I was over-medicated and the Endocrinologist admitted that, "I accept that you have no symptoms of over-replacement with thyroid hormone at the moment (even though the biochemical test suggests over-replacement). He suggested however, that I continue on 50mcg L-T4 and 25mcg L-T3 and offered to continue to monitor me every 3 months.

I remained on this dose until recently when I began to feel very tired and needing a daytime nap again and also feeling inexplicably emotional. Also my weight loss had reached a hiatus. I called and left a message for the Endo who agreed for me to increase to 31.25mcg L-T3 daily and cut L-T4 to 50mcg/25mcg alternate days. I have picked up again and not feeling so tired. I am due blood test results next in December when I also have an appointment with the Endocrinologist.

I would not under any circumstances wish to go back on to L-T4 monotherapy. Although I sometimes feel less than optimal on combination therapy of L-T4/L-T3, the difference in my day to day life is amazing. I no longer fall asleep on the sofa in the evenings. I suffer less with constipation. I have slowly lost some weight whereas before I struggled even to maintain my weight. Since being on L-T3, I have not experienced heartburn and yet this had become a regular occurrence. My blood pressure, pulse and temperature remain very constant. People have noticed that I look well because my face has lost some of that unhealthy puffy appearance.

Case 18 continued

I am incredulous and devastated that NHS England are trying to deprescribe L-T3 as it is essential for some hypothyroid patients like me. I do not see how I can maintain sufficient levels of L-T3 in my body (which is the active hormone and needed for every cell in the body) if I am unable to convert L-T4 to L-T3 efficiently because of the faulty DIO2 gene. I fail to see why I am unable to be prescribed this medicine that I need for life on the NHS. I accept there are cost issues, but since L-T3 is available in other countries at a tiny fraction of the price in the UK (where a monopoly has existed) I am hopeful that this outrageous bad practice of price hiking will be stopped.

Update to Case 18 submitted September 2018

14th September 2018: My Endocrinologist has sent me the results of my T3 ‘all day curve’ test . The reason he gave for the test was to ‘prove’ I am an exception, in order to help him to complete the IFR for T3 on the NHS. This is what he said:

Apologies for the delay in getting back to you regarding your T3 profile from last month. The results came in from the laboratory whilst I was away on annual leave and I have been "playing catch-up" since returning to work earlier this week.

I have attached copies of the results for your perusal. It looks as if your free T3 levels rise very significantly (to twice the upper end of the normal reference range) following your dose of Liothyronine in the morning. As you know, I was wondering whether this day curve was going to show relatively normal free T3 levels (or perhaps only slightly above the upper end of the normal reference range) but, in fact. the levels do seem to peak quite significantly following your dose of Liothyronine. I suspect that if I put this information into your Individual Funding Request, the Panel may suggest that you are being "over-treated". However, as I have explained to you previously, even if I do not provide the information on your free T3 day curve, the Panel is likely to reject the request due to my inability to prove "clinical exceptionality".

I would be grateful if you could mull over the contents of this letter in the next instance and let me know how you feel I should proceed in this matter. As I have also explained to you in the past, it takes me a very significant period of time to complete the very detailed funding request forms and with the enormous amount of work already building-up in my office, I am not sure when I will have the two hours to be able to complete this adequately on your behalf.

NHS letter follows:

Also see Brighton and Hove L-T3 patient information leaflet[13]:

Case 18

Dr & Partners

Dr
Dr
Dr
Dr
Dr
(Specialist Practitioner/Nurse Mgr)

Meridian Surgery
Anchor Healthcare Centre
Meridian Way
Peacehaven
BN10 8NF

Tel: 01273 588200
Fax: 01273 589025

[redacted]

05/04/2018

Dear [redacted],

Thank you for your letter regarding thyroid treatment which was addressed to our practice manager
I am sorry to hear that you have been experiencing problems with treatment of your thyroid disease.

With my limited expertise, I can advise that CCG has taken the decision to blacklist Liothyronine based on lack of cost-effectiveness. I can't answer the question as why Liothyronine is so expensive in 2018 compared to 2007 or compared to Greece, but the data around the effectiveness of Liothyronine is insufficient while cost of it is £20.8 million nationally. I am enclosing the letter which you may have come across from our joint formulary website, about Liothyronine.

BTA advises for patient to stay on Liothyronine on N1 trial, which basically means that you should be monitored by the consultant who will also prescribe it.

I am happy to pass your letter to our Medicines Management team at the CCG for further information.

Please be advised that there is an NHS Complaints Advocate available to help you:

Telephone: 0300 330 5454
Fax: 0330 088 3762
Website: http://nhscomplaintsadvocacy.org

If you are unhappy about any aspect of our response to your complaint, you should contact the parliamentary and health service ombudsman:

Email: phso.enquiries@ombudsman.org.uk
Telephone: 0345 015 4033
Fax: 0300 061 4000
Address: Parliamentary and Health Service Ombudsman
Millbank Tower
Millbank

Appendix 2

NHS documents reviewed[14]

In the local authority and national documents that we reviewed we found the following issues (please note that the counts given relate to the total number of documents reviewed):

1. Seventy seven apply a selective use of the national guidelines. They make blanket assertions that L-T3 is ineffective and therefore cannot be prescribed. These documents fail to include reference to the latest BTA guidance that deals with the small subset of patients who derive clinical benefit from L-T3 treatment, and states clearly that treatment for these patients should not be disrupted.
2. Only ten of those we reviewed are, we believe, in line with the BTA latest guidance - that where a patient derives benefit from the medicine, and has accepted the risks, their treatment should not be disrupted and they do not need to see a specialist endocrinologist.
3. NHS England guidance states that only in ‘exceptional’ cases should patients be prescribed L-T3. The BTA December 2016 guidance included in NHS England's latest guidance provides clarity on this matter. However, 75 documents fail to share this clarity (and in many cases wrongly define exceptionality as being exclusively thyroid cancer patients, patients with liver damage and patients with acute thyroid storm). Thus many patients who qualify for treatment with L-T3 according to national guidance are being told they are not exceptional enough.
4. 10% of the documents we reviewed refer to NHS England’s most recent guidance to CCGs - that decisions regarding ongoing prescribing of L-T3 should be made through an individual patient funding approval process - which is putting undue strain on doctors and patients. Based on the BTA guidance statements of December 2016[3], a decision to continue to prescribe L-T3 should be straightforward and based on the judgement of a specialist clinician or GP.
5. Local authority formulary documents identify L-T3 as a "Do Not Prescribe"/DNP, Black, Red, Red/Restricted, Double Red, Grey, Orange or Amber drug - which is creating barriers for those patients who need it to be prescribed and for doctors who need to be able to prescribe, putting unnecessary pressure in the system. We found this in thirty nine documents, 27% of the total number we reviewed.
6. 50% emphasise the cost of L-T3 and fail to advise caution when switching patients from L-T3 to L-T4, which may result in significant instability of thyroid status and potentially undesirable clinical outcomes which may prove more costly than continuation with L-T3 therapy. (BTA December 2016 guidance[3]).

7. 20% state categorically that L-T3 is no longer available or not licensed for hypothyroidism on the NHS.

8. 36% make reference to other documents that appear to be out of date, inaccurate or irrelevant, such as the PrescQIPP guidance for CCG subscribers[15], long lists of inconclusive small scale research studies or MHRA concerns regarding the quality of L-T3 supply in 2013 which has since been addressed and has also applied to L-T4 supplies in the past so is not relevant, whilst references to the latest BTA 2015 and December 2016 guidance are buried or absent.

9. 44% provide a link to the BTA Hypothyroidism Management Statement from 2015[9] and/or previously issued guidance from the Royal College of Physicians (2011)[16] and/or NICE Clinical Knowledge Summary on Hypothyroidism[17], which was last fully updated in April 2016 but there were no links to the latest BTA December 2016 clarifying guidance statements on L-T3.

10. 21% have no reference at all to BTA guidance.

11. 21% mention the latest BTA guidance on L-T3 but it is buried within lengthy documents rather than highlighted clearly and prominently and has no mention of the key clarifying statements.

12. One document links to https://about.medicinescomplete.com (the Royal Pharmaceutical Society website) for more information. We have requested details of what info on L-T3 is contained on this site but have not yet been advised on this.

13. 16% dictate that L-T3 can only be prescribed in secondary care which is not practical for patients or clinicians and is causing unnecessary logistical and budget management difficulties. National guidance states that L-T3 should only be *initiated* in secondary care which is reasonable for a specialist drug. However, the established practice across the NHS for specialist drugs which are required on an ongoing basis, is for specialists to advise on (and sometimes initially prescribe) and for GPs to then take over prescribing (under shared care agreements). The BTA December 2016 guidance[3] recognises that *"a fraction of patients, especially those who have been on L-T3 treatment for many years, may not attend secondary care clinics [...and…] the BTA position statement should in no way be used as an endorsement for discontinuing L-T3"*.

14. 23% state that all individuals on L-T3 should be reviewed by a consultant, even when patients are stable and well. Dorset Medicines Advisory Group[18] states this review should then take place annually, which may not be practical, given resource limitations in secondary care, or required, according to the BTA guidance which states where a patient is stable and well on L-T3 their treatment should not be changed and a stable patient who does not feel unwell may only need to be reviewed annually by their GP.

15. 29% explicitly advise GPs to review patients on L-T3 and switch them to L-T4 unless they are already under an endocrinologist's care - which is unreasonable when L-T3 is a specialist medicine and treatment should not be changed without an endocrinologist's advice. Five guidance documents state that patients should be switched “if at all possible” rather than if clinically appropriate.

16. 29% contain inaccurate claims about L-T3, such as:

    a) It requires multiple daily doses to maintain steady state
    b) It is the same as L-T4, just more expensive;
    c) Overstating the extent of the evidence for safety of treatment by L-T4 and risks of treatment with L-T3, including referring to specific research studies that are not up to date and have been inconclusive.

    The BTA 2015 statement on Management of Primary Hypothyroidism[9] says: *'There should be recognition that there are not enough data to resolve clinical disagreement amongst thyroid experts (called ‘clinical equipoise’) regarding treatment for hypothyroidism.'*

17. 10% explicitly state that patients who have initially been prescribed privately are not eligible for NHS treatment.

18. Northern Eastern and Western Devon CCG and South Devon and Torbay CCG[19] have a written protocol stating that, “Patients should be clearly told that Endocrinology will not be able to prescribe doses of T3 >10mcg/day". This decision should be left to the discretion of the clinician.

19. Four documents exclude the possibility of L-T3 only treatment (monotherapy). Patient groups would expect that the decision to use monotherapy in exceptional cases should be left to the discretion of the supervising NHS specialist clinician.

20. Twenty eight state categorically that no new patient can be started on L-T3, which excludes new patients who may need it from the possibility of a trial.

21. Page 105 of a 119 page document by North Norfolk Clinical Commissioning Group[20] states that *"CW reported that the prescribing of L-T3 has been stopped for all new patients, this medication isn’t supported by the Royal College of Endocrinologists and cost £250"* (we are not aware that a ‘Royal College of Endocrinologists’ exists and can find no reference to it).

22. Four CCGs report that they follow policies or formularies created by other CCGs rather than national guidance.

23. Two CCGs report they are awaiting further guidance from RMOC (South).

24. Eight further documents from CCGs have been referenced in documents we have reviewed. We have not had sight of these but they should be reviewed by the Department of Health or NHS England.

25. RMOC (South) 3rd May 2018 minutes[21] reported that new L-T3 guidance was in development, however, input, from a limited selection of patient organisations, was only sought for the first time on 12th September, with just one week given to respond to a draft.
26. The PrescQIPP patient information leaflet[22] includes a link stated to be to BTA guidance on L-T3 but which displays an error page when it is clicked. NHS England includes a link to the PrescQIPP patient information leaflet and we query why PrescQIPP's leaflet is shared by NHS England.

A summary table of these points is set out below:

	NHS Liothyronine documents reviewed				Issues																									
	Document	Type	Organisation	Region	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
1	NHS England Items which should not be routinely prescribed in primary care	Guidance (National)	NHS England	National				x		x		x			x			x												
2	BTA Management of primary hypothyroidism: statement by the British Thyroid Association Executive Committee - 2015	Guidance (National)	British Thyroid Association	National			x																							
3	BTA Frequently Asked Questions for GP's 2016	Guidance (National)	British Thyroid Association	National		x																								
4	BTA Frequently Asked Questions for patients 2016	Patient Information	British Thyroid Association	National		x																								
5	BTA Information for Endocrinologists 2016	Guidance (National)	British Thyroid Association	National		x																								
6	PrescQIPP Patient Information Leaflet, changes to prescribing liothyronine	Patient Leaflet (National)	PrescQIPP CIC	National	x					x			x					x		x										x
7	PrescQIPP national guidance - Bulletin 121- Switching liothyronine (L-T3) to levothyroxine (L-T4)	Guidance (National)	PrescQIPP CIC	National	x		x			x		x	x						x	x			x							
8	RCP Statement The diagnosis and management of primary hypothyroidism 2011	Guidance (National)	Royal College of Physicians	National									x																	
9	NICE Clinical Knowledge Summary, Hypothyroidism	Guidance (National)	NICE	National									x																	
10	UKMI 2011 Guidance	Guidance (National)	NHS UK Medicines Information	National									x																	
11	RMOC Liothyronine Guidance (draft)	Guidance (National)	Regional Medicines Optimisation Board (South)	National																									x	
12	NHS Clinical Commissioners statement on L-T3 26 July 2018	National Guidance	NHS Clinical Commissioners	National	x		x						x	x																
13	Airedale Wharfedale and Craven Medicines Formulary	Formulary	Airedale NHS Foundation Trust and Airedale, Wharfedale and Craven CCG	Yorkshire																						x				
14	Ashford, and all of East Kent Prescribing Group liothyronine	Guidelines	East Kent Prescribing Group	East Kent		x						x	x	x																
15	Aylesbury, Vale and Chiltern CCGs Traffic Light List	Formulary	Aylesbury, Vales and Chiltern CCGs	South East England					x																					
16	BHR CCGS email statement on liothyronine	Email Correspondence	Barking and Dagenham, Havering and Redbridge CCGs	South East England									x																	
17	Barnsley CCG summary of NHS England items which should not be routinely prescribed guidance	Guidance	Barnsley CCG	North England			x						x	x																
18	Barnsley CCG T3 Guidance	Guidance	Barnsley CCG	North England					x			x							x											
19	Basildon and Brentwood CCG and Thurrock CCG prescribing liothyronine is not supported	Guidance	Basildon and Brentwood CCG and Thurrock CCG	South East England	x		x	x		x	x	x	x				x	x			x				x					
20	Basildon & Brentwood CCG - Patient information changes to liothyronine prescribing	patient leaflet	Basildon and Brentwood CCG and Thurrock CCG	South East England	x					x			x					x		x										x
21	Bedfordshire and Luton Prescribing Commitee Meeting notes Feb 2016	Meeting minutes	Bedforshire and Luton Prescribing Committee	South East England	x							x	x		x				x					x						
22	Bedfordshire and Luton Prescribing Committee Bulletin 226 - liothyronine (LT3) - Treatment of primary hypothyroidism	Guidance	Bedfordshire and Luton Prescribing Commitee	South East England	x		x			x		x	x	x					x	x										
23	Bedfordshire CCG Minutes of the Finance and Performance meeting with decision on liothyronine prescribing April 2016	Meeting minutes	Bedfordshire and Luton Prescribing Commitee	South East England	x		x			x		x	x	x			x			x										
24	Berkshire West Area Prescribing Committee Policy Statement Liothyronine and Armour Thyroid	Policy statement	Berkshire West Area Prescribing Commitee	South East England	x		x		x	x										x	x									

	NHS Liothyronine documents reviewed				Issues																									
	Document	Type	Organisation	Region	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
25	Berkshire West NHS, Royal Berkshire NHS Foundation Trust, Berkshire Healthcare NHS Foundation Trust, Berkshire West Clinical Commissioning Group	Formulary	Berkshire West NHS, Royal Berkshire NHS Foundation Trust, Berkshire Healthcare NHS Foundation Trust, Berkshire West Clinical Commissioning Group	South East England			x		x	x	x			x						x										
26	Email from Bexley CCG	Email Correspondence	Bexley CCG	South East England										x																
27	Blackpool CCG Position Paper liothyronine	Guidance	Blackpool CCG	North West England	x		x			x				x	x		x		x	x										
28	Bradford Patients CCG patient support	Email Correspondence	Bradford City CCG	North England														x						x						
29	Brent CCG	Email Correspondence	Brent CCG	South East England										x																
30	Information for patients currently treated with liothyronine	Patient Leaflet	Brighton and Sussex University Hospitals	South England	x					x			x					x		x										x
31	Brighton and Hove prescribing Newsletter	Guidance	Brighton and Hove CCG	South England	x					x			x					x		x										x
32	Bromley and all of South East London Red Amber Grey List of drugs not on SEL Formulary	Formulary	South East London	South East England	x		x		x		x		x	x																
33	Bury Clinical Commissioning Group Governing Body, March 2018	Meeting minutes	Bury CCG	North West England	x				x		x			x																
34	Calderdale Clinical Commissioning Group Commissioning Statement	Guidance	Calderdale CCG	North England	x		x			x		x		x						x										
35	Cambridgeshire and Peterborough Joint Prescribing Group. Impact Assessment and Recommendations for reviews produced by external stakeholders, Liothyronine LT-3	Guidance	Cambridgeshire and Peterborough Joint Prescribing Group.	East of England	x		x			x				x	x				x											
36	Cannock Chase CCG, Medicines Optimisation Prescribing Audit, Prescribing Commissioniong Policy	Policy Statement	Cannock Chase CCG	West Midlands							x								x											
37	Canterbury East Kent Prescribing Group liothyronine	Guidelines	Canterbury CCG and East Kent Prescribing Group	South East England		x						x	x	x																
38	Castle Point and Rochford and Southend Clinical Commissioning Groups, Position Statement; The prescribing of liothyronine and Armour Thyroid for the long term treatment of hypothyroidism is not supported.	Position Statement	Castle Point and Rochford and Southend Clinical Commissioning Groups	South East England			x				x		x		x			x			x									
39	NHS Eastern Cheshire Clinical Commissioning Group, NHS South Cheshire Clinical Commissioning Group, NHS Vale Royal Clinical Commissioning Group, Prescribing Commissioning Policy; Liothyronine. Approved by the Area Prescribing Committee on 8 November 2016;	Guidance	NHS Eastern Cheshire Clinical Commissioning Group, NHS South Cheshire Clinical Commissioning Group, NHS Vale Royal Clinical Commissioning Group. Area Prescribing Committee	North West England	x							x	x						x											
40	Prescribing Commissioning Policy; Liothyronine. Approved by the Area Prescribing Committee on 13 March 2018;	Guidance	NHS Eastern Cheshire Clinical Commissioning Group, NHS South Cheshire Clinical Commissioning Group, NHS Vale Royal Clinical Commissioning Group	North West England	x				x	x								x			x			x						
41	City and Hackney CCG re liothyronine prescribing - email	Email Correspondence	City and Hackney CCG	London										x																
42	Decision flowchart for suitablility for shared care guidelines document - City and Hackney CCG and Homerton Hospital Trust	Guidelines	City and Hackney CCG and Homerton Hospital Trust	London													x													
43	Coventry and Warwick liothyronine drug commissioning statement	Guidance	Coventry and Warwickshire Area Prescribing Committee	West Midlands	x		x					x		x						x										
44	Crawley & Horsham - PCN 197-2016 Liothyronine for patients intolerant to levothyroxine	Guidance	Crawley and Horshame CCG	South East England					x																					
45	Croydon Clinical Commissioning Group Governing Body Public Meeting notes 17 January 2017	Meeting Notes	Croydon CCG	South East England														x										x		

	NHS Liothyronine documents reviewed				Issues																									
	Document	Type	Organisation	Region	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
46	Croydon CCG position statement on liothyronine. Not seen. [1]	Guidance	Croydon CCG	South East England																										
47	County Durham and Darlington Grey List	Formulary	Country Durham and Darlington CCG	North East England	x		x						x																	
48	Dartford Gravesham and Swanley CCG updated guidance on liothyronine	Guidance	Dartford Gravesham and Swanley	South East England	x		x						x											x				x		
49	Dartford CCG guidance document, switch protocol and sample patient letter. not seen	Guidance and Patient Letter	Dartford Gravesham and Swanley	South East England																										
50	Derbyshire Joint Area Prescribing Committee (JAPC) Liothyronine not recommended for hypothyroidism. Levothyroxine is the only recommended treatment for hypothyroidism in Derbyshire	Guidance	Derbyshire Joint Area Prescribing Committee	East of England	x		x			x	x	x			x		x							x						
51	Meeting of the South and West Devon Formulary Interface Group Minutes 10 May 2017	Meeting Minutes	Northern Eastern and Western Devon CCG and South Devon and Torbay CCG	West of England					x																					
52	Protocol to review existing patients on L-T3	Guidance	Northern Eastern and Western Devon CCG and South Devon and Torbay CCG	West of England	x		x		x				x					x	x			x		x						
53	Position statement for liothyronine	Position Statement	Dorset CCG, diabetes and endocrinology working group	West of England					x									x						x						
54	Dorset Shared Care guideline for liothyronine	Guidance	Dorset Mecidines Advisory Group	West of England				x																						
55	Dudley CCG Prescribing Policy	Guidance	Dudley CCG	North England						x							x	x												
56	North Durham Formulary	Formulary	County Durham and Darlington Formulary	North East England					x		x																			
57	North East London Formulary	Formulary	Ealing CCG (and all North East London CCGs)	London																										
58	East and North Hertfordshire Medicines Management Committee (HMMC) liothyronine for the treatment of hypothyroidism. RED – Not recommended for prescribing in primary care (New patients)	Guidance	Hertfordshire Medicines Management Committee	East of England	x		x			x		x	x				x		x	x										
59	East Berkshire CCG Effective Prescribing and Performance Group, Policy Number EPG 21	Policy	East Berkshire CCG Effective Prescribing & Performance Group	South East England	x																			x						
60	East Leicestershire and Rutland. Leicester Medicines Strategy Group Treatment of Hypothyroidism with Liothyronine: Guidance for New and Existing Patients	Guidance	Leicestershire Medicines Strategy Group	Midlands		x											x													
61	East of England PAC Guidance Statement Liothyroinine All Indications	Guidance	East of England PAC, a function of PrescQIPP	East of England	x		x			x		x			x		x		x	x	x									
62	Hull and East Riding Prescribing Committee Guidance on the prescribing of liothyronine (T3) and liothyronine - containing products for the management of primary hypothyroidism	Guidance and Patient Letter	Hull and EAst Yorkshire Hospitals Trust	North East England	x		x			x		x	x	x					x	x				x						
63	East Staffordshire Clinical Commissioning Group Prescribing Commissioning Policy 2016	Policy	East Staffordshire Clinical Commissioning Group	West Midlands	x													x												
64	Eastbourne, Hailsham & Seaford CCG, Hastings & Rother CCG, East Sussex Healthcare Trust, East Sussex Area Prescribing Committee, Minutes Wednesday 6 September 2017	Meeting minutes	Eastbourne, Hailsham & Seaford CCG, Hastings & Rother CCG, East Sussex Healthcare Trust, East Sussex Area Prescribing Committee	South of England						x																				
65	Prescribing Commissioning Policy; Liothyronine Approved by the Area Prescribing Committee on 13 March 2018. Prescribing Commissioning Policy Guidance on the Prescribing of Liothyronine	Policy	NHS Eastern Cheshire Clinical Commissioning Group, NHS South Cheshire Clinical Commissioning Group, NHS Vale Royal Clinical Commissioning Group,	North West England	x				x	x			x					x		x	x									
66	North Central London Joint Formulary Commitee Liothyronine in Primary Hypothyroidism Position Statement	Position Statement	North Central London Joint Formulary Committee	London	x		x		x	x	x	x	x						x		x			x						

	NHS Liothyronine documents reviewed				Issues																									
	Document	Type	Organisation	Region	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
67	North Central London Joint Formulary Committee Meeting Minutes 25 august 2016	Meeting Minutes	North Central London Joint Formulary Committee	London	x		x		x	x		x	x		x				x					x						
68	Fareham and Gosport SHIP8 Clinical Commissioning Groups Priorities Committee Draft Policy Recommendation: No. 27 Liothyronine in the Treatment of Primary Hypothyroidism	Policy	Fareham and Gosport CCG	South England			x			x			x						x											
69	Gloucestershire Guidance on the Prescribing of Liothyronine (T3) Containing Products for the Management of Primary Hypothyroidism	Guidance	Gloucester CCG	West England	x		x			x	x	x	x	x					x	x										
70	Great Yarmouth & Waveney prescribing_low_priority_medications_website_wording	Guidance	Great Yarmouth and Waveney	North East England	x		x			x	x		x	x					x											
71	Great Yarmouth and Waveney, North Norfolk, South Norfolk, Norwich and West Norfolk CCGs Joint Strategic Commissioning Agenda Pack 19 June 2018	Meeting Agenda Pack	Norfolk CCGs Group	East of England	x		x		x	x	x	x	x	x			x		x		x					x				
72	Greater Glasgow and Clyde Medicines Formulary	Formulary	Greater Glasgow and Clyde CCG	West of Scotland	x		x			x			x	x			x		x											
73	Greater Huddersfield - Letter-to-Community-pharmacies-from-APC-updated - Feb 18	Guidance	South West Yorkshire APC	South West Yorkshire APC				x		x		x			x			x												
74	Greater Manchester (Stockport) CCG T-3 treatment guideline	Guidance	Stockport CCG	North West England	x		x		x	x	x	x			x		x	x	x	x				x						
75	Greater Manchester GP Updates Prescribing Edition 21 January 2018	Guidance	Stockport CCG	North West England	x		x		x	x	x	x			x		x	x	x	x				x						
76	Hambleton, Richmond and Whitby CCG T3 guidance	Guidance	Hambleton Richmond and Whitby CCG	North East England	x		x			x	x	x	x						x	x										
77	Hambleton Richmondshire & Whitby - Item 16 Appendix 1 TAG Recommendations 24.11.16 NICE Medicines update	Appendix Document	Hambleton Richmond and Whitby CCG	North East England	x		x			x	x	x	x	x					x	x				x						
78	Hambleton Richmond and Whitby CCG, Commissioning Policy on liothyronine November 2016	Policy	Hambleton Richmond and Whitby CCG	North East England	x		x			x	x	x	x	x					x	x				x						
79	Harrogate and Rural District CCG Liothyronine Commissionoing Policy	Policy	Harrogate and Rural District CCG	North East England	x		x			x	x	x	x							x				x						
80	Harrow CCG email	Email Correspondence	Harrow CCG	London				x		x		x			x			x								x		x		
81	Hartlepool & Stockton-on-Tees and South Tees Do Not Prescribe List and Grey List	Guidance	Hartlepool and Stockton on Tees and South Tees CCG	North East England	x		x		x	x	x	x	x	x						x										
82	FOI 26248 HR 09P Subject: Liothyronine Prescribing,Hastings and Rother CCG	FOI request response	Hastings and Rother CCG	South England													x									x	x			
83	Herefordshire Position Statement on liothyronine Jan 2017	Guidance	Herefordshire CCG	West Midlands	x		x	x	x	x		x	x	x				x			x			x						
84	Hetfordshire Medicines Management Committee (HMMC) Liothyronine for the treatment of hypothyroidism RED – Not recommended for prescribing in primary care (New patients)	Guidance	Hertfordshire CCG	East of England	x		x			x		x			x		x		x	x	x									
85	Letter from High Weald Lewes Havens CCG	FOI request response	High Weald Lewes Havens CCG	South England	x		x			x																	x	x		
86	Ipswich and East Sussex T3 Guidelines	Guidance	Ipswich and East Sussex	South East England	x		x			x		x	x						x	x				x						
87	East Kent Prescribing Group liothyronine recommendations	Guidance	Thanet CCG	South East Englad		x						x	x	x																
88	Kernow CCG	Email Correspondence	Kernow CCG	South West England					x																			x		
89	Lancashire Medicines Management Group, Liothyronine Recommendations	Guidance	Lancashire Medicines Management Group	Midlands and North West England	x		x		x	x	x		x	x																

	NHS Liothyronine documents reviewed				Issues																									
	Document	Type	Organisation	Region	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
90	Midlands and Lancashire Commissioning Support Unit New Medicine Recommendation Liothyronine	Guidance	Midlands and Lancashire Commissioning Support Unit	Midlands and North West England																										
91	Leeds CCG Commissioning Policy Prescribing of liothyronine in the long treatment of hypothyroidism	Policy	Leeds North CCG, Leeds South and East CCG and Leeds West CCG	North England	x		x			x		x	x							x										
92	Greater Manchester Mecidines Management Group Minutes of the GM Formulary Subgroup meeting	Meeting Minutes	Greater Manchester Medicines Management Group	North West England	x		x		x	x			x		x	x														
93	Prescribing recommendations - liothyronine (tri-iodothyronine, T3) for thyroid deficiency.	Guidance	Medway CCG and Swale CCG	South East England	x		x			x		x	x						x	x										
94	Mid Essex CCG Policy Statement; Prescribing of liothyronine or unlicensed dried thyroid hormone extracts (Armour Thyroid) is not supported for long term treatment of hypothyroidism	Policy	Mid Essex CCG	South East England	x		x			x		x	x											x						
95	Milton Keynes CCG Information about changes to medicines or treatments on the NHS: Changes to liothyronine prescribing	Patient Leaflet	Milton Keynes CCG	MIdlands			x			x			x					x												
96	Milton Keynes message re: liothyronine prescribing	Email Message	Milton Keynes CCG	Midlands			x			x			x					x	x											
97	North of Tyne and Gateshead Area Prescribing Committee Formulary	Formulary	North of Tyne and Gateshead APC	North East England					x									x												
98	North East Essex letter to patient redacted	Patient Letter	North East Essex CCG	South East England	x		x	x	x	x	x		x							x										
99	North East Essex Prescribing Policy and Guidance for Switching from unlicensed dried thyroid hormone extracts (such as Armour Thyroid) and Liothyronine to Levothyroxine	Policy and Guidance	North East Essex CCG	South East England	x		x			x			x							x										
100	email from North East Hampshire and Farnham CCG re: liothyronine prescribing policy	Email Correspondence	North East Hampshire and Farnham	South East England																				x						
101	Northern Lincolnshire Area Prescribing Committee Formulary email	Email Correspondence	Northern Lincolnshire Prescribing Area Formulary	East Midlands													x													
102	Northern Lincolnshire Area Prescribing Committee Formulary email	Formulary	Northern Lincolnshire Prescribing Area Formulary	East Midlands													x													
103	North Hampshire prescribing policy email	Email Correspondence	North Hampshire	South East England													x													
104	North Kirklees liothyronine policy email	Email Correspondence	South West Yorkshire APC	North England				x		x		x			x			x												
105	North Norfolk CCG Governing Body Meeting in Public 23 May 2017 referencing April meeting minutes	Agenda Pack	North Norfolk CCG	East of England			x			x			x											x						
106	North Norfolk Joint Strategic Commissioning Agenda pack 19 June 2018	Agenda Pack	North Norfolk CCG	East of England	x		x			x		x			x		x		x	x	x									
107	FOI-03406-T6Z8-NS (NHS North Staffordshire CCG)	FOI response	NHS North Staffordshire	West Midlands				x		x		x			x			x												
108	Nottingham City FOI response 1331/18	FOI response		East Midlands																										
109	Nottinghamshire Formulary	Formulary	Nottinghamshire Area Prescribing Committee	East Midlands	x		x		x	x		x	x						x	x			x							
110	Nottinghamshire liothyronine position statement March 2017	Guidance	Nottinghamshire Area Prescribing Committee	East Midlands	x		x		x	x					x			x		x	x									
111	Nottinghamshire Information for Patients currently treated with liothyronine T3	Patient leaflet	Nottinghamshire Area Prescribing Committee	East Midlands	x		x			x	x	x	x						x	x	x			x						
112	Oxfordshire CCG guidance on the prescribing of liothyronine	Guidance	Oxfordshire CCG	South East England	x		x			x		x			x				x					x						
113	Prescribing Points, volume 25, issue 4	Guidance	Oxfordshire CCG	South East England	x		x			x		x			x				x											

	NHS Liothyronine documents reviewed				Issues																									
	Document	Type	Organisation	Region	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
114	Worcestershire APC position statement for treatment: Liothyronine, 'Armour thyroid' and other desiccated thyroid extract products in the management of primary hypothyroidism	Guidance	Worcestershire Area Prescribing Committee	West Midlands	x		x			x		x	x					x		x				x						
115	Worcestershire CCG Prescribing Top Tips liothyronine	Guidance	Worcestershire NHS	West Midlands	x		x			x		x							x											
116	Rotherham CCG email re: liothyronine	Email Correspondence	Rotherham CCG	North England				x		x		x			x			x												
117	Sandwell and West Birmingham changes to prescriptions and medicines	Consultation Paper	Sandwell and West Birmingham	West Midlands	x		x			x	x			x						x										
118	Sheffield Area Prescribing Comitee Traffic Light Drugs List	Formulary	Sheffield CCG	North England			x		x	x				x																
119	Shropshire CCG Information about changes to medicines or treatments on the NHS: Changes to liothyronine prescribing	Patient Leaflet	Shropshire CCG	West Midlands	x		x			x			x					x												
120	Shropshire CCG Formulary Group decision on Prescribing of liothyronine (tri-iodothyronine, T3) and/or desiccated thyroid or thyroid extract products	Guidance	Shropshire CCG	West Midlands	x		x							x																
121	Somerset CCG Minutes of the Prescribing and Medicines Management Group held in Meeting Room 1, Wynford House, Lufton Way, Yeovil, Somerset, on Wednesday, 15 March 2017	Meeting Minutes	Shropshire CCG	South West England					x																			x		
122	Cannock Chase CCG, South East Staffordshire and Selsdon Peninsula CCG, Stafford and Surrounds CCG, East Staffordshire CCG Prescribing Commissioning Policy Summary List A: Drugs not commissioned for prescribing within South Staffordshire - these drugs are not suitable for prescribing locally.	Policy	Cannock Chase CCG, South East STaffordshire and Selsdon Peninsula CCG, Stafford and Surrounds CCG, East Staffordshire CCG	West Midlands			x				x		x						x					x						
123	South West Lincolnshire FOI Request response with PACEF Guidance Droplist Treatment and Clinical Prescribed Medicines February 2017	FOI Response and Guidance	South West Lincolnshire CCG	East Midlands	x		x		x	x	x		x																	
124	St Helen's CCG FOI response	Email and Formulary	St Helen's CCG	North West England		x			x																					
125	Sunderland DROP List	Guidance	Sunderland CCG	North East England	x		x				x			x																
126	Surrey Interim Liothyronine Policy Statement PCN 178 -2015	Policy	Surrey (East Surrey CCG, Guildford & Waverley CCG, North West Surrey CCG, Surrey Downs CCG & Surrey Heath CCG) Crawley and Horsham & Mid-Sussex CCG	South East England		x			x				x																	
127	Swindon Chapter 6 Endocrine dated 2014	Guidance Formulary	Swindon CCG	South East England							x						x													
128	Tameside and Glossop CCG Items not to be prescribed	Guidance	Tameside and Glossop	North West England	x		x		x	x	x									x										
129	Telford and Wrekin CCG commissioning policy liothyronine	Policy	Telford and Wrekin	West Midlands	x		x	x												x										
130	Tower Hamlets FOI response FOI.18.THS030	FOI Response	Tower Hamlets CCG	London	x		x																	x						
131	Trafford CCG email re: liothyronine	Email Correspondence	Trafford CCG	North West England	x		x		x	x	x	x			x		x	x	x	x				x						
132	York and Scarborough Formulary	Formulary	York Teaching Hospitals NHS Foundation Trust, in partnership with Vale of York Clinical Commissioning Group Scarborough and Ryedale Clinical Commissioning Group	North England					x																					
133	Vale of York meeting minutes 18 Jan 2017	Meeting MInutes	York and Scarborough Medicines Commissioning Committee	North East England					x	x			x						x									x		
134	Wakefield OSCAR Online Support Clinical Advice Resource, Items which should not be routingly prescribed in primary care	Guidance	NHS Wakefield and NHS North Kirklees CCGs	North England						x																		x		

	NHS Liothyronine documents reviewed				Issues																									
	Document	Type	Organisation	Region	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
135	Walsall NHS liothyronine prescribing policy	Email Correspondence	Walsall NHS	West Midlands				x		x		x			x			x												
136	Waltham Forest CCG Governing Body Papers 22 March 2017	Governing Body Papers including Meeting Minutes	Waltham Forest CCG	London	x		x			x		x	x						x	x			x							
137	Wandsworth Clinical Commissioning Group Position Statement	Guidance	Wandsworth CCG	London	x		x						x						x		x		x							
138	WECCG Clinical Guidelines and Prescribing Formularies: Chapter 6 Endocrine System	Guidance and Formulary	West Essex CCG	South East England					x								x													
139	West Essex Red List	Formulary	West Essex CCG	South East England	x		x		x	x																				
140	West Hampshire QS11 Optimising therapy for hypothyroidism	Guidance	West Hampshire CCG	South East England	x		x			x			x																	
141	West Kent re: liothyronine prescribing policy	Email Correspondence	West Kent CCG	South East England													x													
142	The Norfolk and Waveney Therapeutics Advisory Group (TAG) Report April 2016 to March 2017	Guidance	Norfolk and Waveney Therapeutics Advisory Group	East of England	x		x			x		x			x		x		x	x	x									
143	West Suffolk CCG Liothyronine Prescribing Policy	Guidance	West Suffolk CCG	South East England	x		x			x		x			x				x	x				x						
144	Wigan DNP Grey list	Formulary	Wigan CCG	North West England				x	x	x		x			x			x												
145	Wirral Guidance on the Prescribing of Liothyronine (T3) Containing Products for the Management of Primary Hypothyroidism	Guidance	Wirral CCG and Wirral University Teaching Hospital	North West England	x	x				x			x						x	x										
146	Wolverhampton CCG Governing Body 13 February 2018 Agenda pack NHS England Consultation on Items which should not routinely be prescribed in Primary Care	Meeting Pack	Wolverhampton CCG	West Midlands				x		x		x	x		x			x												
	Count				77	10	75	14	39	80	29	53	64	31	27	1	24	33	42	43	15	1	4	28	1	4	2	8	1	4
	%				53	7	51	10	27	55	20	36	44	21	18	1	16	23	29	29	10	1	3	19	1	3	1	5	1	3

Appendix 3

Suggested Patient Pathway

The pathway below has been prepared by ITT, Thyroid UK and Thyroid Patient Advocacy updated with small suggestions from the Midlands Thyroid Support Group, the Thyroid Trust and the British Thyroid Association.

1 New patients currently undergoing a primary care trial of L-T3

Trial is allowed to continue under the care of the GP. If the trial is successful, care to continue under care of GP. This will minimise disruption to the patient. If trial is not successful referral to a thyroid specialist endocrinologist in secondary care with clear criteria on what constitutes successful.

2 New patients currently undergoing a secondary care clinical trial of L-T3

Trial is allowed to continue under the care of a thyroid specialist endocrinologist to minimise disruption to patient and secondary care. If trial is successful, care to be taken over by GP with clear criteria on what constitutes successful.

3 Patient de-prescribed L-T3 by an endocrinologist (secondary care) against patient's wishes

If due to CCG protocol, patient is to have L-T3 reinstated immediately and care passed to primary care. This is based on the recommendation of the British Thyroid Association (December 2016)[3] who advise that a change in treatment can result in significant instability in thyroid status which can actually cost more to address than continuing with L-T3.

4 Patient de-prescribed L-T3 by a GP against patient's wishes

If due to CCG protocol, patient is to have L-T3 reinstated immediately and care reinstated in primary care. This is based on the recommendation of the British Thyroid Association (December 2016)[3] who advise that a change in treatment can result in significant instability in thyroid status which can actually cost more to address than continuing with L-T3.

5 Patient transferred from NHS prescription to a named patient prescription by a GP

If clinical need has been established (either primary or secondary), but L-T3 has been deprescribed due to CCG protocol, the patient is to have L-T3 reinstated immediately.

6 Patients who have been de-prescribed L-T3 by the GP without referral to a thyroid specialist endocrinologist against patient's wishes

The British Thyroid Association (December 2016)[3] advise that a change in treatment with L-T3 can result in a significant instability in thyroid status, which can take some time to address.

Therefore, in patients who are stable and well on L-T3 and who wish to continue taking, treatment is not disrupted.

If the patient, on removal of L-T3, has become symptomatic and an increase in dose of L-T4 has not restored euthyroid state the GP should reinstate L-T3 prescription.

7 Patients established on L-T3 who are prescribed by NHS GP or endocrinologist

Option 1:
(Recommended) If the patient is well established and blood tests (including FT3) indicate thyroid levels are well managed, do not review. Care to be continued in primary care without referral. This will minimise secondary care resources and disruption to the patient.

Option 2:
Paper review of the patient by GP. Clear criteria provided for use in the review by GP (see below) and may then be reviewed by a thyroid specialist endocrinologist.

Option 3:
Face to face secondary care patient review. Clear criteria for this should be set out (see below). This option is not recommended because of the disruption to patients and resource impact on secondary care.

8 Patients who have not been prescribed L-T3 but are symptomatic and may require thyroid specialist endocrinologist review

When a patient remains symptomatic despite normal TSH and FT4 tests, national guidelines recommend referral to a thyroid specialist endocrinologist and FT3 testing. While some patient groups would also like testing for T3/T4 ratios and rT3 to be undertaken and genetic test results to be taken into consideration to establish clinical need, it is noted that the BTA has suggested that these criteria are controversial. Currently, hard evidence in favour of these criteria is lacking and it is our understanding that they are not currently included in any guidelines (e.g. European Thyroid Association, (ETA)) for combination L-T4/L-T3 treatment.

Thyroid blood tests are typically conducted every 6-8 weeks when establishing treatment dose. To expedite treatment and minimise secondary care burden, where patients have obtained recent private blood tests, these are accepted to speed up the treatment of patients.

9 Patients who have been prescribed L-T3 by a private endocrinologist

Where a patient opts to pay for private care, their entitlement to NHS services remains and should not be withdrawn. Patients who have had L-T3 initiated by a private endocrinologist and who are deriving benefit from it and are stable should be transferred to primary care for continuation of L-T3 treatment. Treatment with L-T3 is not outside normal clinical practice.

10 Patients who have procured their own L-T3
The patient is referred to secondary care for review by a thyroid specialist endocrinologist.

11 Patients who have had a secondary care review and who have been recommended L-T3 but GP has refused prescription
If secondary care has established clinical need tor L-T3, treatment should be passed to primary care. If GP continues to refuse to prescribe L-T3, treatment regime should remain and continue in secondary care.

12 Patient unhappy with result of review.
If a patient is unhappy with the outcome of a review there should be a right to appeal and a second referral made to a named endocrinologist

To limit repeat referrals, patients should have the right to request a different endocrinologist if the one they are referred to is known not to have the specialist knowledge required.

Proposed criteria for patient assessments

A. Confirmation from GP that patient had previously been prescribed L-T4 monotherapy but remained symptomatic.
B. Confirmation that GP or endocrinologist attempted to optimise the L-T4 dose prior to prescription of L-T3.
C. Provide test results of TSH, FT4 and FT3.
D. Some patient groups would also like to see testing of the T4/T3 ratio and where the T4/T3 ratio is low, testing of rT3. However, it is noted that the BTA has suggested that these criteria are controversial. Currently, hard evidence in favour of these criteria is lacking and it is our understanding that they are not currently included in any guidelines (e.g. ETA) for combination T4/T3 treatment
E. Provide comparison of levels of symptoms on L-T4 to L-T4 plus L-T3.
F. Patient self-assessment of their health and wellbeing on L-T4 plus L-T3.
G. Some patient groups would also like to explore whether there is a genetic predisposition to poor conversion providing any corroborating test results. However, it is noted that the BTA has suggested that these criteria are controversial. Currently, hard evidence in favour of these criteria is lacking and it is our understanding that they are not currently included in any guidelines (e.g. ETA) for combination L-T4/L-T3 treatment.
H. Check for other underlying conditions that mean a patient may not absorb L-T4, such as gut issues or any other conditions that may be causing symptoms. Provide any corroborating test results.
I. Check to see if there has been a reduction in other non-thyroid treatments as a consequence of treatment with L-T3.
J. Check to see if other medications have been altered which may account for the reduction in symptoms.

Appendix 4

Detailed Review of the 'East of England PAC Guidance Statement, liothyronine all indications' document.

The East of England Priorities Advisory Committee (PAC), (which is a function of PrescQIPP), supplied a copy of the East of England PAC Guidance Statement, "Liothyronine (all indications)"[23], document to Thyroid Support Group Norfolk.

A few days after this, a joint and detailed review of the document was carried out by Thyroid Support Group Norfolk, ITT, TUK and TPA patient groups and sent to PAC in August 2018[24]. The patient groups agreed that it was so extensively problematic that it required a prompt response, to flag up that it contained serious issues.

The PAC document appears to be based on PrescQIPP Bulletin 121[15], which does not seem to be in line with NHS England guidance[2] or British Thyroid Association (BTA) guidance[3]. Both of these recognise that a small but significant number of patients, despite having 'normal' thyroid function tests, do not feel well on L-T4 alone.

The BTA states that clinical need should come before financial considerations and they therefore do not support the practice of sudden withdrawal of L-T3 therapy. They state that "Patients established on L-T3 who continue to derive benefit from its use should continue to use it".[3]

We believe that both the PAC document and the PrescQIPP Bulletin 121 are being used in many local guidance documents to inform CCGs around the country.
Therefore it is necessary to raise concerns

The main concerns raised in the review are as follows:

- The statement that, "Levothyroxine monotherapy is the treatment of choice for hypothyroidism. There is no consistent evidence to support the routine use of liothyronine in the management of hypothyroidism, either alone or in combination with levothyroxine." In fact, there is published evidence to support the use of liothyronine for treating hypothyroidism.

- The list regarding the criteria for accessing funding for liothyronine is incomplete.

- There is a lack of clarity around:

    a) who should initiate treatment
    b) who has clinical responsibility for ongoing prescribing of liothyronine and
    c) who has clinical responsibility for the switching of patients to levothyroxine if clinically appropriate

- There are errors and omissions in the background and key points section of the guidance such as incorrectly referring to L-T4 as an active hormone, the use of out-dated clinical papers and omitting reference to the 2016 BTA guidance.

Due to the above concerns and lack of references to support other statements, the PAC guidance needs to undergo an *independent* review at the earliest opportunity.

Appendix 5

Analysis of NHS England open prescribing data for L-T3

Dr Peter Taylor MRCP MSc PhD, of the Thyroid Research Group at Cardiff University, has analysed NHS England open prescribing data[25] and identified widespread variation in L-T3 prescriptions per 1000 L-T4 prescriptions by CCG - revealing almost a 50 fold variation between CCGs.

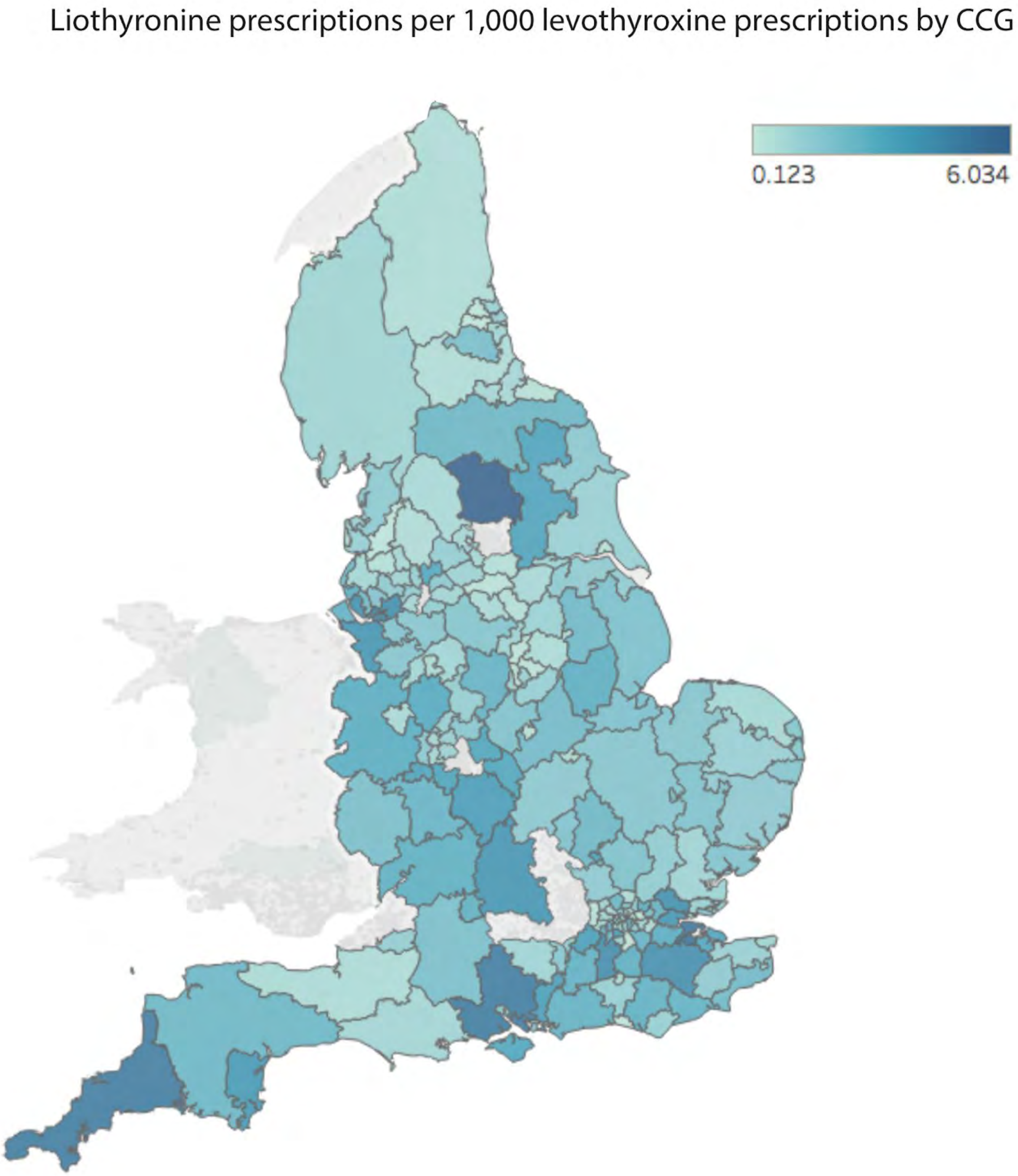
On the map in figure 1 below, the brighter the colour the more T3 prescriptions.

The graphs in figure 2 and 3 show changes in median L-T3 prescribing over time - and how it relates to total cost of L-T3 each month. As price rises, L-T3 prescriptions fall.

Figure 3 shows how less L-T3 is given in CCGs where there are greater levels of deprivation and is a powerful illustration of significant health inequality for thyroid patients in poorer areas.

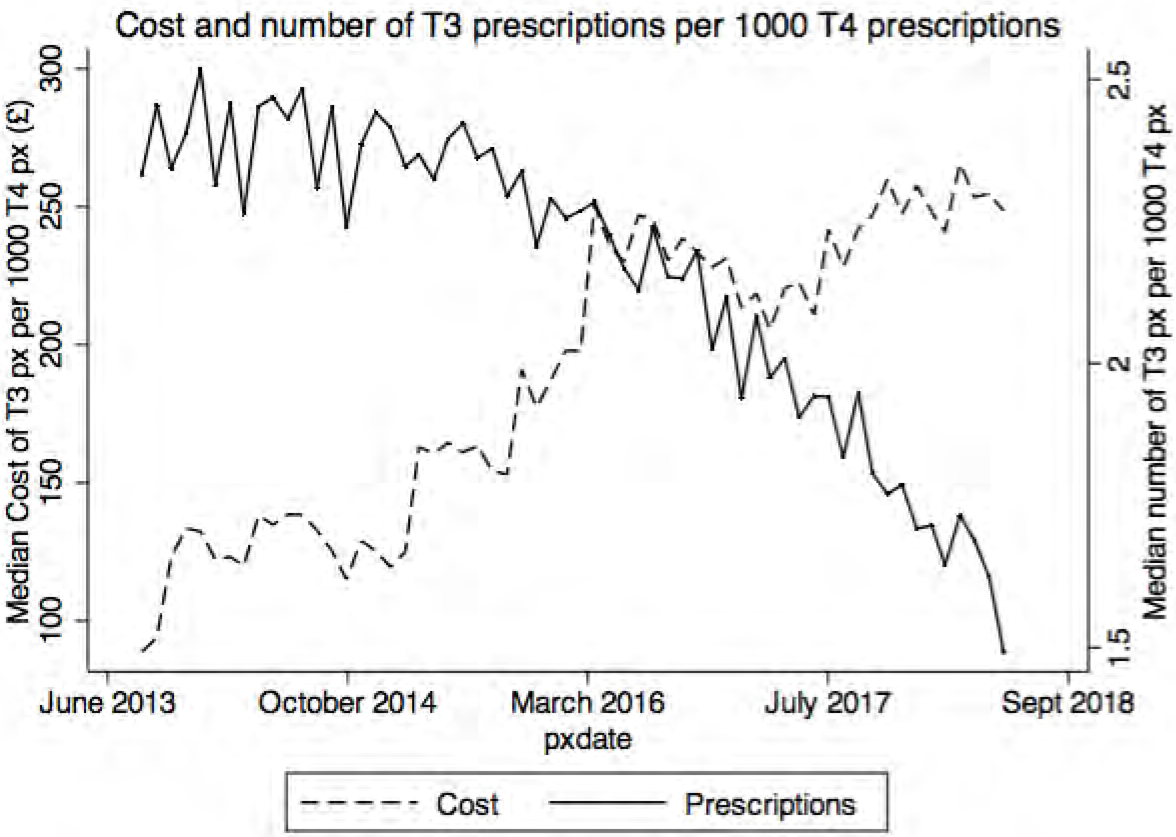
Manuscript submitted for publication.

Figure 1



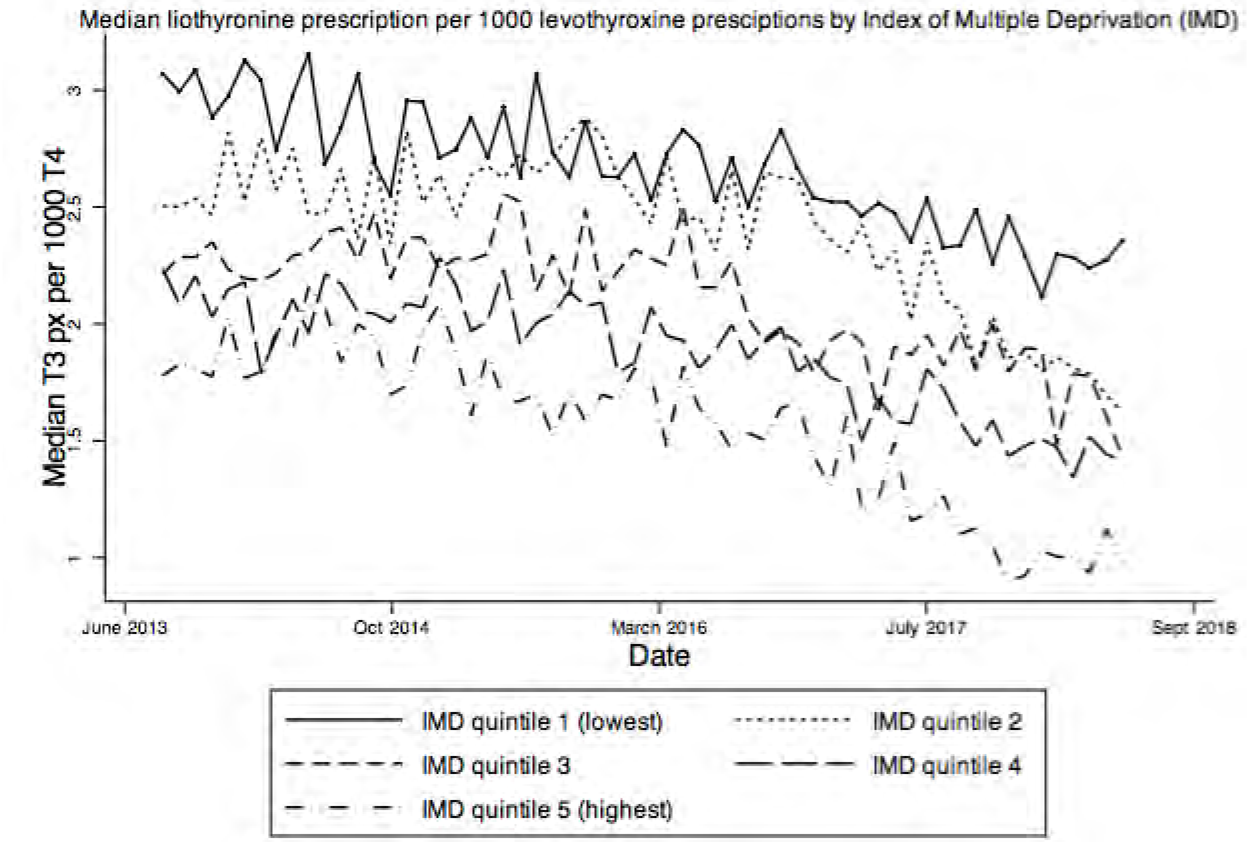
OpenPrescribing.net, EBM DataLab, University of Oxford, 2017, analysis by Dr Peter Taylor, Thyroid Research Group, Cardiff University. Map created by Tableau Software

Figure 2



OpenPrescribing.net, EBM DataLab, University of Oxford, 2017, analysis by Dr Peter Taylor, Thyroid Research Group, Cardiff University

Figure 3



OpenPrescribing.net, EBM DataLab, University of Oxford, 2017, analysis by Dr Peter Taylor, Thyroid Research Group, Cardiff University.

Appendix 6

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14. NHS documents reviewed. The national documents can all be viewed here: https://drive.google.com/open?id=1jNDH7SdZPwevMygnoV3fmFr3CnDtroZ0 The local documents can all be viewed here: https://drive.google.com/open?id=1vs7gxKYFvJD09Lh7Zi4Oa4KaaNU7qpN7.uk/media/1364/patient-information-changes-to-liothyronine-prescribing.pdf
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The Thyroid Trust, 15 Great College Street, London, SW1P 3RX (Working towards registering as a Charitable Incorporated Organisation)

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