2022

T3 Prescribing Survey

An update on the inequitable situation faced by thyroid patients in England who require liothyronine for treatment of hypothyroidism.









13th June 2022

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Introduction

Liothyronine (T3) is a generic medicine, licensed and used for many decades, which some patients with hypothyroidism need to be well. All national guidance recognises that it is appropriate for a cohort of patients, those who do not do well on levothyroxine alone and are shown to benefit from liothyronine after initiation by an NHS specialist. And yet around the country most Clinical Commissioning Groups have policies in place which are causing harm to patients by denying treatment. In those cases where this has occurred, patients have resorted to the private sector or to informal means, such as buying the medication online, or even travelling abroad where it is sometimes available to buy over the counter, to source the medicine they need which the NHS should be providing.

It is likely that many more patients are not benefitting from levothyroxine, since many are unable to go to the lengths required to push for liothyronine, or are not aware that T3 could be an option for them. Symptoms of poorly managed hypothyroidism can include depression, other cognitive impairment and crippling fatigue as well as significant weight gain, muscle weakness and a general inability to participate fully in day to day activities and work which can further affect their mental health. People's lives are being blighted and it is time for decisive action to resolve this matter.

The inequitable situation outlined in this report was last reported to the Department of Health and Social Care (DHSC) and NHS England in March 2021, in a report by The Thyroid Trust entitled Information on the Status of Adoption of National Guidance on Liothyronine Prescribing by CCGs in England, and in February 2020 in the first T3 Prescribing Survey Report, produced by a consortium of thyroid patient groups. Before that it was highlighted in the Liothyronine Dossier 'Case Details with Clear Evidence that NHS England Guidance on Prescription of Liothyronine is not Being Followed by CCGs report of 2018', which was compiled by patient groups, advised by the British Thyroid Association, at the request of Lord O'Shaughnessy following the Regret debate led by Lord Hunt in the House of Lords on 20th June 2018.

The Liothyronine Dossier led to the Regional Medicines Optimisation Committee (RMOC) revising their Prescribing Guidance for Liothyronine, to make it clearer that T3 treatment should not be withheld from the cohort of patients who may benefit.

Since the publication of the RMOC guidance, NHS England have given repeated assurances that it will be strongly communicated to local health authorities, and the expectation reiterated to them that they are expected to follow it. Yet from the evidence it is clear that the situation is worsening, not improving. And this is despite continued falls in price since the conclusion of the Competition and Markets Authority Investigation (2021), which issued fines in excess of £100m to the original licence holder and their backers, for charging excessive and unfair prices for liothyronine between 2009 and 2017.

Disappointingly for patients, NICE guideline NG145 does not actively make recommendations for liothyronine - but it does include a link to the RMOC prescribing guidance. NICE guidelines are not intended to be comprehensive or to replace either clinical judgement or patient centred care. Hence the onus for making treatment decisions on when and how to use liothyronine, in cases of hypothyroidism that have unambiguously not benefited from levothyroxine alone, has to lie with experienced specialist clinicians whose patients give their informed consent. Worryingly, none of the CCGs who reference the NICE guideline in their formulary policies do so correctly. Consequently, they are not following national guidance, and clinicians are being prevented from exercising their professional judgement in respect of the cohort of patients who are not adequately treated on levothyroxine alone.

Executive Summary

This survey was conducted to ascertain if there had been a change in the prescribing practices of Clinical Commissioning Groups (CCGs) in England since the liothyronine prescribing survey in February 2020 and the status of guidance adoption review in early 2021. The authors are aware that due to NHS restructuring, all CCGs will be replaced by Integrated Care Systems (ICSs) and Integrated Care Boards (ICBs) in due course and some have already transitioned. The report authors are clear that the issues with CCGs which this data has flagged up must be addressed by any remaining CCGS, or the ICS or ICB which takes over their responsibilities. The purpose of this report is to highlight to NHS England and DHSC that

- patients are still being denied an important treatment that their clinicians have prescribed for them
- access to it is unfairly and inconsistently applied across different parts of the country and
- decisive action to resolve this matter is urgently required.

NHSE RMOC prescribing guidance states "The prescribing of liothyronine is only supported if initiated by, or considered appropriate following a review by, an NHS consultant endocrinologist. The withdrawal or adjustment of liothyronine treatment should also only be undertaken by, or with the oversight of, an NHS consultant endocrinologist. The RMOC therefore recommends that strict criteria are applied to ensure that liothyronine is only prescribed in the situations where alternative treatments have been found to be inadequate." In addition, the NICE guideline NG145 links to the NHSE RMOC liothyronine prescribing guidance. The British Thyroid Association, the professional body for thyroid specialists, has produced separate guidance, which states clearly that a patient established and well on T3 should not have their treatment disrupted to avoid the risk of them being made significantly unwell for a prolonged period. All this relevant guidance is summarised and linked to later in this document. See Appendix J for all references.

The price of T3 (20 mcg) is now over 75% lower than when it was included in the 2017 NHS Consultation 'Items which should not routinely be prescribed in primary care'. The latest price (i.e. £63 for a pack of 28 x 20mcg tablets from Advanz, and around £200 less than it was at its peak) does not support the continued categorisation of T3 as a high cost drug.

This survey results show that the national guidance continues to be used by only a limited number of CCGs.

58% (61) of CCGs are still continuing to withdraw, refuse or reduce T3 prescriptions across England. Most CCGs have not adopted RMOC or NICE guidance as the basis of their T3 prescribing policies and are incorrectly interpreting national guidance.

Summary of findings

106 CCG websites were reviewed. The names of the CCGs were obtained from the NHS Clinical Commissioners' website. The data is from the CCG websites or published formularies. See the Tables of Data section of this document for full lists of CCGs and the issues identified in each of them. Note that there are policies with a number of exclusions. The main themes are analysed.

The key findings are:

1. 61 of 106 (58%) CCGs have not adopted RMOC or NICE in full and have policies that are not in line with national guidance.

- 2. 38 of the 106 (36%) CCG policies found and reviewed had policies that seem to be in line with national guidance. The remaining 7 CCG (6%) websites or formularies either did not include sufficient information on the prescribing policy or the information could not be found.
- 3. Of the 38 CCGs (36%) that have policies which appear to broadly follow national guidance, 13 have additional conditions which mean they are either not fully compliant, and treatment can either be very hard to get, or is not always sufficient for patient needs in these areas.
 - a. 13 CCGs (12%) require a Shared Care Agreement to be in place between secondary care and the patient's GP. This involves a formal process to sign off the transfer of prescribing responsibilities. While RMOC guidance includes a sample Shared Care Agreement and says that use of one 'may be appropriate', these arrangements are only usually required for new drugs or drugs with high levels of complexity; liothyronine is neither of these and RMOC does not require a Shared Care Agreement. Creating one is an additional administration burden for the NHS and for health professionals. Patients frequently report difficulty accessing these arrangements where they exist.
 - b. Some CCGs state that, if the GP is not willing to take on prescribing, then it remains in secondary care. GPs may be being pressurised by the CCG not to take on prescribing responsibility, which puts further burden on specialists and creates an additional barrier for patients.
 - c. 25 CCGs (24%) permit care to be transferred from secondary care to the patient's local GP without agreement.
- 4. Of the 61 CCGs (58%) where the policy is very clearly not in line with national guidance, the main reasons are:
 - a. 12 CCGs (11%) have a 'do not prescribe', a 'not on formulary', a 'deprescribe' or 'prior prescribing committee approval required' policies on liothyronine.
 - b. 27 CCGs' (25%) state that prescribing is only in secondary care and the patient will not be subsequently treated locally by their GP. This is entirely unreasonable and a poor use of resources for a medicine likely to be taken for life and where a patient is expected to be mostly stable and well while taking it.
 - c. 7 CCGs (6%) have a policy that only permits prescribing in the event of extreme symptoms in hospital only which fails to recognise the cohort of patients identified in national guidance who require liothyronine for treating hypothyroidism long term.
 - d. 22 CCGs (21%) do not allow new patients to be prescribed liothyronine. Patients are reporting being told by NHS specialist clinicians in London that they need liothyronine but must travel to Greece to buy it.
- 5. Of the 106 CCGs, only 15 (14%) reference the 2019 NICE guideline and none are in line with national guidance. This indicates that the NICE guideline is unclear.
- 6. The RMOC guidance has not been adopted by 80 (75%) CCGs. RMOC is referenced by 26 CCGs as the basis of their policies, but 10 of these are not in fact in line with it.
- 7. A majority of CCGs reference guidance that is out of date and which has been superseded by the 2019 NICE guideline.

8. 3 CCGs have policies restricting the amount of T3 that can be prescribed, below that of the BNF national formulary. This rationing of patients' doses of medication is not in line with national guidance. (this explanation is needed before Recommendations 1c.)

Recommendations

- 1. All CCGs, and Integrated Care Boards in future, adopt national guidance:
 - a. RMOC guidance as recommended by NICE is adopted by all CCGs as the prescribing policy for liothyronine.
 - b. The Norfolk and Waveney CCG's liothyronine patient pathway is adopted by all CCGs. The Norfolk and Waveney pathway has been approved by their appropriate CCG policy governance and correctly adopts NICE, NHS England and RMOC guidance. This is a cost effective and expedient way to ensure national guidance is adopted by all CCGs.
 - c. Liothyronine dosing to be prescribed according to the national formulary and patient need, and not limited by CCGs.
- 2. National guidance for thyroid drug prescribing (including liothyronine) is simplified to ensure CCGs correctly interpret its formulary policies. This should include:
 - a. a clearer statement in the main body of the 2019 NICE guideline linking to the RMOC liothyronine prescribing recommendations
 - b. CCGs which currently insist on Shared Care Agreements remove the need for administrative processes such as Shared Care Arrangements to ease the administrative burden for healthcare professionals and streamline provision of service where appropriate.
- 3. **Liothyronine is removed from the high cost items monitored by Open Prescribing:** At the current cost of £63 (a 75% reduction since its inclusion in 2017), it is no longer a high cost drug.

A brief overview of national guidance

- 1. In 2016, the British Thyroid Association, the endocrinologists' professional body, (BTA) issued guidance on switching patients from liothyronine (T3) to levothyroxine for those patients who do not require T3, while stating very clearly that some patients require T3 to be well and that those who had been stable and well on T3 should not have it removed. BTA Liothyronine Statements and FAQs
- 2. In November 2017, the NHS England Medicines Optimisation Consultation 'Items Which Should Not Be Routinely Prescribed in Primary Care' (updated June 2019) advised CCGs that 'Due to the significant costs associated with liothyronine and the limited evidence to support its routine prescribing in preference to levothyroxine, the joint clinical working group considered liothyronine suitable for inclusion in this guidance. However, during the consultation, we heard and received evidence about a cohort of patients who require liothyronine and the clinical working group felt it necessary to include some exceptions based on guidance from the BTA.' Items which should not routinely be prescribed in primary care 2019
- 3. In June 2019, the NHSE Regional Medicines Optimisation Committee (RMOC) published updated T3 prescribing guidance via the NHSE Specialist Pharmacy Service, with comprehensive information for clinicians and CCGs. The NHSE SPS RMOC guidance confirmed the BTA and NHS England guidance that T3 is useful for a particular cohort of patients, i.e. those who do not thrive on levothyroxine alone. This was published after the Liothyronine Dossier, a report produced by patient groups supported by the BTA, which evidenced the harm being done to patients by CCGs not following the 2017 NHS England guidance. RMOC Liothyronine Prescribing Guidance June 2019
- 4. In November 2019, NICE produced its NG145 Guideline Thyroid Disease: Assessment and Management. This guideline states that it is not meant to be comprehensive or replace clinical judgement or patient centred care, hence it does not detail when T3 should be prescribed, simply recommending that it should not be <u>routinely</u> prescribed. It signposts to the RMOC prescribing guidance in the 'Rationale and impact' section which means it is easily missed. 'Routinely' means it is not first-line treatment, but it does not mean that it cannot be prescribed. NICE emphasises the importance of patient centred care. Unfortunately, NICE were unable to make strong specific recommendations for T3, due to a lack of evidence from large scale randomised clinical trials, which is disappointing, yet should not mean that clinicians cannot prescribe. NICE NG145 Hypothyroidism Guideline
- 5. Patient groups were particularly hoping for greater clarity from NICE on the question of when T3 should be prescribed. But this is sadly largely missing from the guideline, and the link to the RMOC prescribing guidance for T3 is not prominent. NICE have stated they were unable to consider the body of evidence submitted by patient groups and clinicians demonstrating positive patient experiences and a lack of harm with T3, including the Liothyronine Dossier, when the guideline was developed. The NICE process prioritises evidence from clinical trials. The trials conducted to date, into T3, have been inconclusive, with unreliable results due to small sample sizes and other issues. However, there are large scale population studies which are more informative which should not be overlooked and demonstrate both patient satisfaction and long term safety.
- 6. As both T3 and levothyroxine have been around for many decades, neither has been subject to the kind of large scale randomised clinical trials that would provide the level of evidence required for NICE to make strong recommendations. Therefore, the onus for making treatment decisions, on when and how to use liothyronine in cases of hypothyroidism that have unambiguously not benefited from levothyroxine alone, will continue to lie with experienced specialist clinicians whose patients give their informed consent. NICE states: "Decisions about treatment and care are best when they are made together. Your doctor should give you clear information about the benefits and risks of

- treatments, talk with you about your options and listen carefully to your views and concerns." NICE references the RMOC guidance and the understanding is that, if NICE refers to something, then NICE supports it.
- 7. Patient groups recommend that NICE move their link to the RMOC prescribing guidance for T3; from the 'Rationale and impact' section to the main body of their guideline. It is currently being missed and its apparent absence may be used to justify denying treatment.
- 8. The wording NICE have used is as follows: 'NHS England's specialist pharmacy service has produced advice on prescribing liothyronine.' It would be very useful if this could be added to the end of point 1.3.4 in the guideline, instead of only being visible in the rationale and impact section on managing primary hypothyroidism.
- 9. See Appendix F for instructions on how to find the current reference, which patient groups have found it necessary to provide to patients and clinicians who have not been able to find it.
- 10. It would be better still for patients if the following proposed wording could be added as an additional paragraph to the NICE guideline: "The majority of patients living with hypothyroidism can be treated effectively with levothyroxine alone, but it is recognised that there is a cohort of patients who require liothyronine. NHSE Specialist Pharmacy Service has produced national prescribing guidance for the small proportion of patients who require liothyronine in order to maintain health and wellbeing. The NHSE SPS guidance can be found here."

https://www.sps.nhs.uk/wp-content/uploads/2019/07/RMOC-Liothyronine-guidance-V2.6-final-1.pdf

PrescQIPP

Many CCGs began limiting access to liothyronine (T3) following 2016 DROP List advice from PrescQIPP, a not for profit organisation funded by the NHS, that provides Medicines Optimisation advice to CCGs which subscribe to their service.

NB: PrescQIPP advice is not official guidance and is only available to their subscribers.

The DROP List in 2016 advised that all patients on T3, and other treatments on the list, should have their prescription reviewed and discontinued if it was not required. Unfortunately, many CCGs were overly zealous with their reviews, failing to follow good practice and overlooking patients' needs. Many prescriptions which should have continued were stopped, which was the start of all the access issues patients have been suffering since then. Four CCGs are still referencing PrescQIPP and all four are not in line with national guidance.

The report authors hope that PrescQIPP will now consider producing an updated bulletin for the prescription of T3, particularly as increased competition is now likely to continue to drive down prices. It should be noted, however, that the NHS and DHSC both clearly state that patients should not be denied this medication if they need it, regardless of the Drug Tariff price.

An Approved Patient Pathway

Norfolk and Waveney CCG Patient pathway and governance of national guidance.

In May 2020, Norfolk and Waveney CCG approved a clear patient pathway for prescribing T3 to those patients who require it, after three years of hard work by local patients from the Thyroid Support Group Norfolk, supported by Healthwatch Norfolk and national thyroid patient organisations. Patient groups are now calling for all CCGs to adopt the Norfolk pathway to ensure access to T3 in all areas of the country, thereby ending the harm currently being caused to patients whose treatment has been withheld.

Norfolk & Waveney CCG Liothyronine Pathway Approved May 2020

Lord Bethell's 2020 statement in House of Lords

In February 2020, in response to a House of Lords written question by Lord Hunt of Kings Heath, Lord Bethell, who was then Parliamentary Under Secretary of State at the DHSC said:

"Representatives of NHS England and NHS Improvement and NHS Clinical Commissioners met with representatives from the Thyroid Trust, Healthwatch England, Lord Hunt of Kings Heath and Lord Borwick of Hawkshead on 13 February 2020. NHS England and NHS Improvement will clarify guidance within the National Health Service system. This guidance will set out that the recommendation of the clinical working group was that liothyronine should not be routinely prescribed in primary care; but there may be circumstances where prescribing of the medication is clinically appropriate for individual patients as determined by endocrinologists providing NHS services, after a carefully audited trial of at least three months duration of the medicine." Parliament-Lords Written Question Liothyronine 12.2.2020

Detailed findings

A. Status on whether CCG policies meet national guidance

Policy meets national guidance	Number of CCGs	% of CCGs
No - CCG policy does not meet national guidance	61	58%
No information found	7	6%
Yes - CCG policy meets national guidance	38	36%
Total	106	100%

The table sets out if the CCG policy is in line with national guidance or not:

- No: The policy is not considered consistent with national guidance in 61 (58%) CCGs.
- Yes: the CCG policy was found to be consistent with national guidance in 38 (36%) CCGs. This includes 13
 CCGs where a formal Shared Care Arrangement is required to transfer patients to their local GP for
 prescribing.
- No information found: The CCG policy was not found, or was not accessible to non-CCG employees, in 7 (6%) CCGs.

B. Analysis of the CCG policies - count only

The first section of the table below sets out why the number of CCG policies shown are not in line with national guidance. The CCGs are named in the data tables section of this report.

- Deprescribe: 1 CCG has a policy that requires patients to be de-prescribed regardless of whether it is clinically appropriate.
- Do not prescribe: 5 CCGs have policies that state liothyronine is not to be prescribed.
- Hospital only: 7 CCG policies allow prescribing only in extreme circumstances in a hospital setting. The
 type of permitted use in these CCG policies include myxoedema coma, where rapid treatment is required,
 and in preparation for thyroid ablation, completely failing to recognise the national guidance for
 hypothyroidism when levothyroxine has failed.
- Prior approval required from prescribing committee: 1 CCG requires endocrinologists to obtain approval if they consider prescribing liothyronine for a patient. This is not in line with national guidance, undermining clinicians' judgement, and not to mention an extraordinary use of their valuable time.
- No new patients: 13 CCGs do not permit prescribing to new patients.
- Not on formulary for prescribing: 5 CCGs did not include liothyronine, an approved drug, on their formulary for prescribing.
- Secondary care: the prescribing is retained in secondary care and is not transferred back to a local GP. This
 is not in line with national guidance which states that prescribing can be transferred back to a GP after a 3
 month trial. This is another example of putting extraordinary and unnecessary pressure on secondary
 care services.
- Existing patients in secondary care and no new patients: 7 CCGs only permit existing patients to access prescribing in secondary care and also do not permit treatment with liothyronine for new patients.
- Shared care agreement required for existing patients and no new patients: 2 CCGs require existing
 patients to be prescribed through a shared care arrangement and do not permit prescribing to new
 patients.

The second section of the table sets out the CCGs that have policies in line with national guidance.

- Shared Care: 13 CCGs only permit prescribing where a Shared Care Arrangement is in place.
- 25 CCGs follow national guidance and transfer the patient from secondary care to their local GP. While the RMOC provides a sample Shared Care Agreement and states that using one may be appropriate, patients frequently report difficulty accessing these arrangements. Some CCGs only permit them for existing patients and have a 'do not prescribe' policy on new patients. Others state that if the GP is not willing to take on prescribing under a Shared Care Agreement, then it remains in secondary care.

Local guidance issues highlighted in this report	Number of CCGs	% CCGs
Deprescribe	1	1%
Do not prescribe	5	5%
Hospital only	7	6%
Prior approval Prescribing Committee	1	1%
No new patients	13	12%
Not on formulary for prescribing	5	5%
Secondary only for all patients	20	19%
Existing patients in secondary care and no new patients	7	6%
Shared care agreement required for existing patients and no new patients	2	2%
Total not in line with national guidance	61	58%
Number of CCGs which are in line with national guidance, with and without a Shared Care Agreement requirement	Number of CCGs	% CCGs
Shared Care arrangement required	13	12%
Yes and SCA is not required	25	24%
Total in line with national guidance	38	36%

C. Status of the adoption of RMOC and NICE

The table below sets out the referenced guidance used by CCGs for their formulary policy. The latest guideline is listed where a CCG has referenced more than one guidance.

- Only 15 (14%) CCGs reference the 2019 NICE guideline. All these CCGs are not in line with national guidance. RMOC is only mentioned by 2 of the CCGs.
- RMOC guidance has been referenced in their policies by 26 CCGs. Of these, 15 correctly applied national guidance, but 11 did not.

- 2015 BTA statement is referenced by 9 of the 106 CCGs. Of the 9 CCGs that reference the 2015 BTA statement, 4 CCGs do not have a prescribing policy in line with national guidance. 5 have a policy that is in line with national guidance.
- 'Items not routinely prescribed in primary care' references the 2017 NHS England consultation of that name as their policy by 23 of the 106 CCGs. However, of these, 8 CCG policies are not in line with that national guidance.
- No information was found for the basis of 22 CCGs' policies. These CCG policies did not state a reference for their liothyronine policy or were inaccessible to non-CCG employees. Formularies for prescribing policies were reviewed and 19 of these were not in line with national policy.
- The PrescQIPP Drugs to Review for Optimised Prescribing (DROP) list is referenced by 4 CCGs. All are not in line with national guidance. The PrescQIPP bulletin was followed by updated national guidance.

Guidance quoted	Not in line National Guidance	In line National Guidance	Total number CCGs
NICE	15	0	15
RMOC	11	15	26
2015 BTA statement	4	5	9
Items not routinely prescribed	8	15	23
No reference	19	3	22
PrescQIPP DROP	4	0	4
Total	61	38	99
Policies not found			7
Grand Total	61	38	106

D. The reasons why CCG policies are not following national guidance

The table below sets out the reasons why the policies of the non-compliant CCGs are not in line with national guidance, together with the policy that is referenced.

Why not national guidance	2016 BTA guidance	NHSE Items not routinely prescribed	NICE	No reference found	PrescQIPP DROP	RMOC	Total CCGs
Not on formulary / deprescribe / no new patients	2	5	15	6	2	4	34
Hospital / extreme symptoms	0	1	0	3	1	2	7
Secondary Care only	2	2	0	10	1	5	20
Grand Total	4	8	15	19	4	11	61

- BTA 2016 guidance is incorrectly interpreted by 4 CCGs: 2 CCGs as 'do not prescribe' or do not allow prescribing to new patients, and 2 CCGs incorrectly have a policy that liothyronine is only prescribed in secondary care.
- The 2017 consultation 'Items which should not be routinely prescribed': 2 CCGs only allow
 prescribing in secondary care, 5 CCGs have 'do not prescribe'/'deprescribe/'no new patients'
 policies, 1 CCG policy is for prescribing in extreme circumstances in hospital setting only which
 simply fails to recognise that some patients require liothyronine on an ongoing basis as part of
 their day to day treatment for hypothyroidism.
- NICE is incorrectly interpreted by all 15 CCGs.
- 19 CCGs did not have a reference for their policy. 10 of the CCGs allowed prescribing in secondary care only, 6 CCGs had liothyronine as 'not on formulary'/'do not prescribe'/'deprescribe', and 3 CCGs only permit prescribing in a hospital setting for extreme symptoms.
- PrescQIPP 2016 Drugs to Review for Optimised Prescribing (DROP) List is referenced by 4 CCGs. It
 appears this guidance was wrongly taken to mean drop/do not prescribe. 2 CCGs' policies are
 secondary care only, 1 in extreme hospital setting only, 1 CCG has a 'do not prescribe'/'not on
 formulary' / 'no new patients' policy. The PrescQIPP list was followed up by the later NHSE
 guidance.
- RMOC is incorrectly interpreted by 11 CCGs: 5 CCGs have a 'prescribe in secondary care only', 2
 CCGs allow prescribing in a hospital setting for extreme myxoedema coma secondary care only,
 and 4 CCGs have liothyronine as 'not on formulary'/'do not prescribe'/'deprescribe'.

Note on the basis of the preparation of this data

This data is for England only. The liothyronine policy status was obtained by searching websites for the formularies and policies of each CCG. The prescribing status of the CCGs has not been confirmed in writing with the CCGs. There are limitations in the collation of data. The data may not be fully up to date because not all formularies were easily identifiable or available to public access. Status may have changed since the policy was reviewed in January 2022.

Appendices

A) Tables of data

Table 1: List of CCGs that meet national guidance

NHS Bassetlaw CCG: 02Q	1
NHS Bath and North East Somerset, Swindon and Wiltshire CCG: 92G	1
NHS Berkshire West CCG: 15A	1
NHS Birmingham and Solihull CCG: 15E	1
NHS Black Country and West Birmingham CCG: D2P2L (former CCGs: NHS Dudley CCG, NHS Sandwell and West Birmingham CCG, NHS Walsall CCG and NHS Wolverhampton CCG)	1
NHS Bradford District and Craven CCG: 36J	1
NHS Brighton and Hove CCG: 09D	1
NHS Calderdale CCG: 02T	1
NHS Cannock Chase CCG: 04Y	1
NHS Derby and Derbyshire CCG: 15M	1
NHS East Leicestershire and Rutland CCG: 03W	1
NHS East Riding of Yorkshire CCG: 02Y	1
NHS East Staffordshire CCG: 05D	1
NHS East Sussex CCG: 97R	1
NHS Hampshire, Southampton and Isle of Wight CCG: D9Y0V (former CCGs: NHS Fareham and Gosport CCG, NHS Isle of Wight CCG, NHS North Hampshire CCG, NHS South Eastern Hampshire CCG, NHS Southampton City CCG and NHS West Hampshire CCG)	1
NHS Herefordshire and Worcestershire CCG: 18C	1
NHS Herts Valleys CCG: 06N	1
NHS Hull CCG: 03F	1
NHS Ipswich and East Suffolk CCG: 06L	1
NHS Kent and Medway CCG: 91Q	1
NHS Kirklees CCG: X2C4Y (former CCGs: NHS Greater Huddersfield CCG and NHS North Kirklees CCG)	1
NHS Leeds CCG: 15F	1

NHS Lincolnshire CCG: 71E	1
NHS Newcastle Gateshead CCG: 13T	1
NHS Norfolk and Waveney CCG: 26A	1
NHS North Cumbria CCG: 01H	1
NHS North Staffordshire CCG: 05G	1
NHS North Tyneside CCG: 99C	1
NHS North Yorkshire CCG: 42D	1
NHS Northumberland CCG: 00L	1
NHS Oxfordshire CCG: 10Q	1
NHS Somerset CCG: 11X	1
NHS South East Staffordshire and Seisdon Peninsula CCG: 05Q	1
NHS South Tyneside CCG: 00N	1
NHS Stafford and Surrounds CCG: 05V	1
NHS Stoke on Trent CCG: 05W	1
NHS Sunderland CCG: 00P	1
NHS Vale of York CCG: 03Q	1
Grand Total	38

Table 2: List of CCGs with policies that do not meet national guidance

NHS Barnsley CCG: 02P	1
NHS Bedfordshire, Luton and Milton Keynes CCG: M1J4Y (former CCGs: NHS Bedfordshire CCG, NHS Luton CCG and NHS Milton Keynes CCG)	1
NHS Blackburn with Darwen CCG: 00Q	1
NHS Blackpool CCG: 00R	1
NHS Bolton CCG: 00T	1
NHS Bristol, North Somerset and South Gloucestershire CCG: 15C	1
NHS Buckinghamshire CCG: 14Y	1
NHS Bury CCG: 00V	1
NHS Cambridgeshire and Peterborough CCG: 06H	1

NHS Castle Point and Rochford CCG: 99F	1
NHS Cheshire CCG: 27D	1
NHS County Durham CCG: 84H	1
NHS Coventry and Warwickshire CCG: B2M3M (former CCGs: NHS Coventry and Rugby CCG, NHS South Warwickshire CCG and NHS Warwickshire North CCG)	1
NHS Devon CCG: 15N	1
NHS Doncaster CCG: 02X	1
NHS Dorset CCG: 11J	1
NHS East and North Hertfordshire CCG: 06K	1
NHS East Lancashire CCG: 01A	1
NHS Frimley CCG: D4U1Y (former CCGs: NHS East Berkshire CCG, NHS North East Hampshire and Farnham CCG and NHS Surrey Heath CCG)	1
NHS Fylde and Wyre CCG: 02M	1
NHS Gloucestershire CCG: 11M	1
NHS Greater Preston CCG: 01E	1
NHS Halton CCG: 01F	1
NHS Heywood, Middleton and Rochdale CCG: 01D	1
NHS Knowsley CCG: 01J	1
NHS Leicester City CCG: 04C	1
NHS Liverpool CCG: 99A	1
NHS Manchester CCG: 14L	1
NHS Mid Essex CCG: 06Q	1
NHS Morecambe Bay CCG: 01K	1
NHS North Central London CCG: 93C	1
NHS North East Essex CCG: 06T	1
NHS North East Lincolnshire CCG: 03H	1
NHS North Lincolnshire CCG: 03K	1
NHS Northamptonshire CCG: 78H	1
NHS Nottingham and Nottinghamshire CCG: 52R	1
NHS Oldham CCG: 00Y	1

NUIC Downson out h CCC 10D	1
NHS Portsmouth CCG: 10R	1
NHS Rotherham CCG: 03L	1
NHS Salford CCG: 01G	1
NHS Sheffield CCG: 03N	1
NHS Shropshire, Telford and Wrekin CCG: M2L0M (former CCGs: NHS Shropshire CCG and NHS Telford and Wrekin CCG)	1
NHS South East London CCG: 72Q	1
NHS South Sefton CCG: 01T	1
NHS South West London CCG: 36L	1
NHS Southend CCG: 99G	1
NHS Southport and Formby CCG: 01V	1
NHS St Helens CCG: 01X	1
NHS Stockport CCG: 01W	1
NHS Surrey Heartlands CCG: 92A	1
NHS Tameside and Glossop CCG: 01Y	1
NHS Tees Valley CCG: 16C	1
NHS Thurrock CCG: 07G	1
NHS Trafford CCG: 02A	1
NHS Warrington CCG: 02E	1
NHS West Essex CCG: 07H	1
NHS West Leicestershire CCG: 04V	1
NHS West Suffolk CCG: 07K	1
NHS West Sussex CCG: 70F	1
NHS Wigan Borough CCG: 02H	1
NHS Wirral CCG: 12F	1
Grand Total	61

Table 3: List of CCGs where policy does not permit prescribing of T3 for new patients

NHS Bolton CCG: 00T	1
NHS Bristol, North Somerset and South Gloucestershire CCG: 15C	1
NHS Bury CCG: 00V	1
NHS Castle Point and Rochford CCG: 99F	1
NHS County Durham CCG: 84H	1
NHS Dorset CCG: 11J	1
NHS Heywood, Middleton and Rochdale CCG: 01D	1
NHS Manchester CCG: 14L	1
NHS Mid Essex CCG: 06Q	1
NHS North Central London CCG: 93C	1
NHS North East Essex CCG: 06T	1
NHS Oldham CCG: 00Y	1
NHS Salford CCG: 01G	1
NHS Southend CCG: 99G	1
NHS Stockport CCG: 01W	1
NHS Surrey Heartlands CCG: 92A	1
NHS Thurrock CCG: 07G	1
NHS Trafford CCG: 02A	1
NHS Warrington CCG: 02E	1
NHS West Essex CCG: 07H	1
NHS West Sussex CCG: 70F	1
NHS Wigan Borough CCG: 02H	1
Grand Total	22

Note: some of the CCGs have exclusions for existing patients and new patients.

Table 4: List of CCGs with a hospital only policy

NHS Bedfordshire, Luton and Milton Keynes CCG: M1J4Y (former CCGs: NHS Bedfordshire CCG, NHS Luton CCG and NHS Milton Keynes CCG)	1
NHS Buckinghamshire CCG: 14Y	1
NHS Cambridgeshire and Peterborough CCG: 06H	1
NHS East and North Hertfordshire CCG: 06K	1
NHS Gloucestershire CCG: 11M	1
NHS North East Lincolnshire CCG: 03H	1
NHS North Lincolnshire CCG: 03K	1
Grand Total	7

Table 5: List of CCGs with a 'deprescribe', 'not on formulary' or 'approval required prior to treatment' policy

NHS Blackburn with Darwen CCG: 00Q	1
NHS East Lancashire CCG: 01A	1
NHS Greater Preston CCG: 01E	1
NHS Morecambe Bay CCG: 01K	1
NHS Northamptonshire CCG: 78H	1
NHS Nottingham and Nottinghamshire CCG: 52R	1
NHS Portsmouth CCG: 10R	1
NHS Sheffield CCG: 03N	1
NHS Shropshire, Telford and Wrekin CCG: M2L0M (former CCGs: NHS Shropshire CCG and NHS Telford and Wrekin CCG)	1
NHS South East London CCG: 72Q	1
NHS Tameside and Glossop CCG: 01Y	1
NHS West Suffolk CCG: 07K	1
Grand Total	12

Table 6: List of CCGs whose policy allows prescribing in Secondary Care only

NHS Barnsley CCG: 02P	1
NHS Blackpool CCG: 00R	1
NHS Cheshire CCG: 27D	1
NHS Coventry and Warwickshire CCG: B2M3M (former CCGs: NHS Coventry and Rugby CCG, NHS South Warwickshire CCG and NHS Warwickshire North CCG)	1
NHS Devon CCG: 15N	1
NHS Doncaster CCG: 02X	1
NHS Frimley CCG: D4U1Y (former CCGs: NHS East Berkshire CCG, NHS North East Hampshire and Farnham CCG and NHS Surrey Heath CCG)	1
NHS Fylde and Wyre CCG: 02M	1
NHS Halton CCG: 01F	1
NHS Knowsley CCG: 01J	1
NHS Leicester City CCG: 04C	1
NHS Liverpool CCG: 99A	1
NHS Rotherham CCG: 03L	1
NHS South Sefton CCG: 01T	1
NHS South West London CCG: 36L	1
NHS Southport and Formby CCG: 01V	1
NHS St Helens CCG: 01X	1
NHS Tees Valley CCG: 16C	1
NHS West Leicestershire CCG: 04V	1
NHS Wirral CCG: 12F	1
Grand Total	20

In addition, there are CCGs which allow prescribing in secondary care only for existing patients and also state that no new patients can be prescribed liothyronine

NHS Bristol, North Somerset and South Gloucestershire CCG: 15C	1
NHS Castle Point and Rochford CCG: 99F	1
NHS County Durham CCG: 84H	1

NHS Mid Essex CCG: 06Q	1
NHS Southend CCG: 99G	1
NHS Thurrock CCG: 07G	1
NHS Warrington CCG: 02E	1
Grand Total	7

Table 7: List of CCGs whose policy restricts the amount of T3 that can be prescribed - rationing patients' dose of medication, not in line with national guidance

NHS Buckinghamshire CCG: 14Y
NHS Devon CCG: 15N
NHS East & North Herts 06K

Table 8: List of CCGs where RMOC is explicitly adopted and the overall policy meets national guidance

NHS Berkshire West CCG: 15A	1
NHS Bradford District and Craven CCG: 36J	1
NHS Calderdale CCG: 02T	1
NHS East Leicestershire and Rutland CCG: 03W	1
NHS East Riding of Yorkshire CCG: 02Y	1
NHS Herts Valleys CCG: 06N	1
NHS Hull CCG: 03F	1
NHS Kent and Medway CCG: 91Q	1
NHS Kirklees CCG: X2C4Y (former CCGs: NHS Greater Huddersfield CCG and NHS North Kirklees CCG)	1
NHS Leeds CCG: 15F	1
NHS Norfolk and Waveney CCG: 26A	1
NHS North Cumbria CCG: 01H	1
NHS North Yorkshire CCG: 42D	1
NHS Oxfordshire CCG: 10Q	1

NHS Vale of York CCG: 03Q	1
Grand Total	15

Table 9: List of CCGs where NICE is explicitly adopted, but the overall policy does not meet national guidance

NHS Bolton CCG: 00T	1
NHS Bury CCG: 00V	1
NHS Castle Point and Rochford CCG: 99F	1
NHS Heywood, Middleton and Rochdale CCG: 01D	1
NHS Manchester CCG: 14L	1
NHS Mid Essex CCG: 06Q	1
NHS North Central London CCG: 93C	1
NHS Oldham CCG: 00Y	1
NHS Salford CCG: 01G	1
NHS South East London CCG: 72Q	1
NHS Southend CCG: 99G	1
NHS Stockport CCG: 01W	1
NHS Thurrock CCG: 07G	1
NHS Trafford CCG: 02A	1
NHS Wigan Borough CCG: 02H	1
Grand Total	15

Table 10: List of CCGs who reference RMOC, but their policy is not in line with national guidance

NHS Bristol, North Somerset and South Gloucestershire CCG: 15C	1
NHS Buckinghamshire CCG: 14Y	1
NHS County Durham CCG: 84H	1
NHS Coventry and Warwickshire CCG: B2M3M (former CCGs: NHS Coventry and Rugby CCG, NHS South Warwickshire CCG and NHS Warwickshire North CCG)	1
NHS Dorset CCG: 11J	1

NHS East and North Hertfordshire CCG: 06K	1
NHS Leicester City CCG: 04C	1
NHS Nottingham and Nottinghamshire CCG: 52R	1
NHS South West London CCG: 36L	1
NHS Tees Valley CCG: 16C	1
NHS West Leicestershire CCG: 04V	1
Grand Total	11

Table 11: List of CCGs who have a shared care policy

Note: While RMOC includes a sample Shared Care Agreement which the guidance says 'may be appropriate', it is not a requirement of the RMOC prescribing guidance, and patients frequently report difficulty accessing these arrangements. Some CCGs only permit them for existing patients and have a 'do not prescribe' policy on new patients. Others state that, if the GP is not willing to take on prescribing, then it remains in secondary care; it appears that CCGs may be pressurising GPs to refuse care - unreasonably putting the burden for life long prescribing for patients who are stable

and well back on to a stretched specialist service.

NHS Bath and North East Somerset, Swindon and Wiltshire CCG: 92G	1
NHS Berkshire West CCG: 15A	1
NHS Bradford District and Craven CCG: 36J	1
NHS Brighton and Hove CCG: 09D	1
NHS Calderdale CCG: 02T	1
NHS Derby and Derbyshire CCG: 15M	1
NHS East Riding of Yorkshire CCG: 02Y	1
NHS East Sussex CCG: 97R	1
NHS Hampshire, Southampton and Isle of Wight CCG: D9Y0V (former CCGs: NHS Fareham and Gosport CCG, NHS Isle of Wight CCG, NHS North Hampshire CCG, NHS South Eastern Hampshire CCG, NHS Southampton City CCG and NHS West Hampshire CCG)	1
NHS Herts Valleys CCG: 06N	1
NHS Hull CCG: 03F	1
NHS Leeds CCG: 15F	1
NHS Somerset CCG: 11X	1
Grand Total	13

B) Open Prescribing data – Items prescribed and declining spend as cost has come down

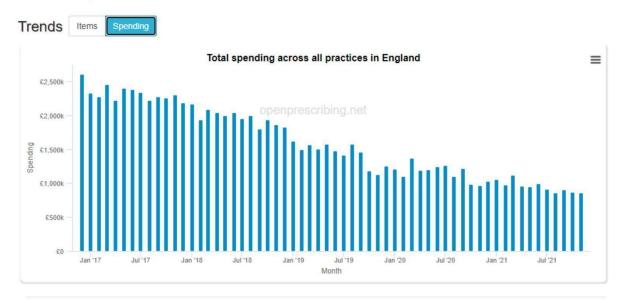
https://openprescribing.net/chemical/0602010M0/

Liothyronine sodium (0602010M0)

Part of chapter 6 Endocrine System, section 6.2 Thyroid and antithyroid drugs, paragraph 6.2.1 Thyroid hormones

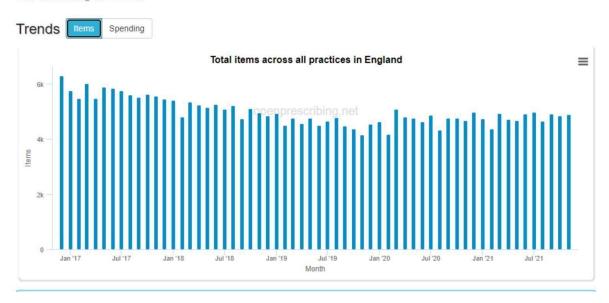
High-level prescribing trends for Liothyronine sodium (BNF code 0602010M0) across all GP practices in NHS England for the last five years. You can see which CCGs prescribe most of this chemical relative to its class, or learn more about this site.

View all matching dm+d items.



High-level prescribing trends for Liothyronine sodium (BNF code 0602010M0) across all GP practices in NHS England for the last five years. You can see which CCGs prescribe most of this chemical relative to its class, or learn more about this site.

View all matching dm+d items



B.1) The Norfolk and Waveney CCG experience of Actual Costs

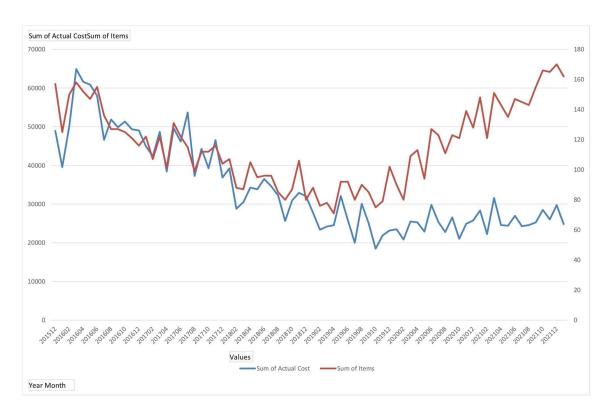
In April 2022, Thyroid Support Group Norfolk leaders met with Michael Dennis, the Norfolk and Waveney CCG Head of Medicines Optimisation. He provided important commissioning data.

The data shows a timeline of the cost to the CCG of commissioning liothyronine (T3) over a time period of 7 years, commencing in 2015 when the CCG began seeking to limit prescriptions of T3 following on from the PrescQIPP DROP list, and the inflated price at that time.

The graph demonstrates that commissioning T3 in accordance with NHSE guidelines led to an increased number of patients who are able to receive this crucial medicine. And at the same time the CCG has clearly reduced its spending as a result of the decrease in the cost of T3.

The report authors hope that this important data will give confidence to those remaining CCGs who are reluctant to commission T3 in line with the national guidance.

Norfolk and Waveney CCG have kindly permitted this data to be published in this report.



Sum of Actual costs of Items, liothyronine prescribing in Norfolk and Waveney CCG, 2015 – 2022. Data kindly shared by the CCG April 2022.

C) Patient reports to NHS England

Patients and specialist medical practitioners have been campaigning to resolve issues of restricted access to liothyronine for over five years, since the price peaked, producing three major reports prior to this one:

- In October 2018 the dossier: 'Liothyronine Case Details with Clear Evidence that NHS England Guidance on Prescription of Liothyronine is not Being Followed by CCGs' was produced by a consortium of UK thyroid patient organisations, advised by the British Thyroid Association. It was requested by Lord O'Shaughnessy the then Parliamentary Under-Secretary (Department of Health and Social Care) and submitted to NHSE. <u>Liothyronine Dossier October 2018</u>
- 2. In February 2020, the consortium produced 'T3 Prescribing Survey Report', requested by Lord Hunt of Kings Heath. This shows that, even after NHS England's T3 prescribing guidance was clarified by request of the Parliamentary Under-Secretary for Health, at least 46% of CCGs were still restricting access to T3 at that time.
 - T3 Prescribing Survey Report February 2020
- In March 2021, The Thyroid Trust produced a further draft report 'Information on the Status of Adoption of NHS England and NICE Guidance on Prescribing of Liothyronine by CCGs, which was sent to Lord Bethell. <u>Information on the status of adoption of NHS England and NICE guidance on prescribing of liothyronine by CCGs</u>

D) Ongoing patient reports

Patient groups continue to receive regular reports from many patients across the country who are being denied treatment with liothyronine and, as a result, are experiencing ongoing highly debilitating symptoms and high levels of distress. This leads some to self-treat at their own expense and on their own initiative, which can also be dangerous and is clearly not an option for the majority who are simply being left to suffer. The quotes below are representative of what affected patients are telling patient groups:

"My NHS Endocrinologist agreed to a 3 month trial but said he wouldn't be able to prescribe any more regardless of any health improvements. He said he can't understand why the NHS will not agree to treatment. My local CCG say liothyronine is not available on the NHS."

"My NHS endocrinologist [in a leading London teaching hospital] told me to go to Greece to buy liothyronine because he could only support use, but not prescribe it. He didn't want GP to pass costs on to him."

E) Referrals issues and pressure on secondary care

Patient groups are concerned at the additional pressure on endocrinology secondary care as the result of the bureaucracy which prevents clinicians from being able to prescribe according to their clinical judgement. An examination of NHS Referrals data from NHSE Referrals Service Open Data in February 2022 reveals:

- 1. 190k gap between referrals asked for and bookings made for endocrine and metabolism (there is no subcategory for thyroid disorders). Total referrals were 345k and booked referrals were 155k in the period November 2019 January 2022. This equals a 190k gap.
- 2. Bookings are currently about 2k a week (referrals about 3.8k week), so 190k constitute 95 weeks of bookings to make on top of the new referrals.
- 3. The gap between what has been referred and been accepted started at the pandemic in March 2020 and has never corrected itself. The gap has remained about 50% (the number of bookings is half the referrals) for 2 years.
- 4. The gap in endocrine is approximately 7 10% more than the trend in all specialties (33% for all at end of January 2022 versus 41% for endocrine). While it is understandable that priority areas are more likely to be cancer, heart and diabetes, endocrine patients' conditions are also serious and it is not reasonable to expect endocrine patients who require specialist treatment to simply not get it, particularly if the pressure on the system is in part caused by artificially created barriers.
- 5. There is a clear need for specialist endocrinology services which is not being met for GPs or patients.

 Most referrals will be for diabetes but an unknown number will be thyroid patients seeking liothyronine.
- 6. Patient groups would prefer to see secondary care resources focused on urgent and 2 week care with routine follow up; thus ongoing prescribing of T3 when patients are stable and well should not need to go back to secondary care, unless there is an issue with the patient's health.
- 7. If there are around 11,000 patients in the UK taking T3, and most may be stable and well, it seems nonsensical for secondary care providers to continually have to confirm their need for their ongoing prescription. After an initial assessment, further reviews in secondary care should only be required if the patient becomes unwell.

Patients frequently comment that they are waiting 12 months for an appointment or follow up, meanwhile living with an impaired quality of life and or under enormous stress, fearing that their prescription will be removed.

F) How to find the NICE Thyroid Guideline link to NHSE SPS RMOC Liothyronine Prescribing Guidance

The NICE Guideline refers commissioners and clinicians to the RMOC 'Guidance - Prescribing of Liothyronine'. The guideline contains two links to the RMOC prescribing guidance, depending on how the guideline is being accessed. The understanding is that, if NICE references something, then NICE supports it. Patient groups would very much like NICE to revise their guideline, as described in point 8 on page 8 of this report, to end the pernicious situation whereby patients are being denied the treatment they need because the NICE position on liothyronine is being misinterpreted.

Link 1

https://www.nice.org.uk/guidance/ng145

- Download guidance as PDF
- Go to Page 34 Managing primary hypothyroidism
- Recommendations 1.3.3 to 1.3.7
- Go to Page 35 'Why the committee made these recommendations' and at end of first paragraph, the link 'advice on prescribing liothyronine' leads to the RMOC prescribing guidance for liothyronine.

Link 2

NB When reading the guideline in a web browser, rather than as a pdf, the link is only in the NICE Rationale and Impact section https://www.nice.org.uk/guidance/ng145/chapter/Rationale-and-impact

- Scroll down to read the section: Managing primary hypothyroidism Recommendations 1.3.3 to 1.3.7 and follow the link to the

Recommendations | Thyroid disease: assessment and management | Guidance | NICE

- Why the committee made the recommendations
- Thyroid hormone replacement
- At end of first paragraph it says: "NHS England's specialist pharmacy service has produced <u>advice on prescribing</u> <u>liothyronine</u> This link leads to the RMOC liothyronine prescribing guidance

G) NICE response to stakeholder comments

In response to stakeholders' comments, including NHS England, to the draft NICE guideline when it was published, that the July 2019 RMOC detailed Prescribing Guidance was not included in the NICE draft guideline where NICE says 'Do not routinely offer liothyronine for primary hypothyroidism', the response from NICE to each comment was:

'A footnote has been added to the rationale and impact section for the recommendation 1.3.4 on liothyronine cross referring to the latest Regional Medicines Optimisation Committee (RMOC) guidance issued to Clinical Commissioning Groups (CCGs) on the prescribing of liothyronine'

https://www.sps.nhs.uk/wpcontent/uploads/2019/07/RMOC-Liothyronine-guidanceV2.6- final-1.pdf

Sadly this response from NICE has proven to be unsatisfactory, since stakeholders report constantly having to explain to healthcare providers where they can find the link. Moreover, this report finds that every CCG which references NICE in their local guidance is not following the national prescribing guidance and patients are still being unfairly denied treatment.

J) References

- a) NHSE Medicines Optimisation Programme guidance, which concluded liothyronine should continue to be available to patients who require it Items which should not routinely be prescribed in primary care 2019
- b) NHSE Regional Medicines Optimisation Committee (RMOC) guidance <u>RMOC Liothyronine Guidance June</u> 2019
- c) NICE NG145 Guideline Thyroid Disease: Assessment and Management <u>NICE NG145 Guideline November</u> 2019
- d) NHS England statement February 2020 Parliament-Lords Written Question Liothyronine 12.2.2020
- e) Norfolk and Waveney CCG liothyronine patient pathway Norfolk & Waveney CCG Liothyronine Pathway Approved May 2020
- f) Current price https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff
- g) British Thyroid Association Current Guidance on switching from liothyronine to levothyroxine which includes a clear directive that patients who benefit from liothyronine and are known to have previously not benefited from levothyroxine alone should not be switched https://www.british-thyroid-association.org/current-bta-guidelines-and-statements
- h) The liothyronine dossier 2018 bit.ly/LiothyronineDossier2018
- i) The T3 Prescribing survey 2020 https://www.thyroidtrust.org/uploads/3/1/8/1/31816005/t3 prescribing survey report 7.2.20.pdf
- j) Status of Adoption of liothyronine national guidance by CCGs 2021 https://www.thyroidtrust.org/uploads/3/1/8/1/31816005/information on the status of adoption of n hs england and nice guidance on prescribing of liothyronine by ccgs v6.4.pdf
- k) PrescQIPP https://www.prescqipp.info/
- NHSE Referrals Service Open Data https://digital.nhs.uk/dashboards/ers-open-data

ends.

Improve Thyroid Treatment Campaign Group, 29 Gaynor Close, Wymondham NR18 0EA Thyroid Support Group Norfolk, Stillwater Farm, Rabbit Lane, Great Witchingham, Norfolk, NR9 GB The Thyroid Trust, 15 Great College Street, London, SW1P 3RX Registered Charity Number 1183292 Thyroid UK, 32 Darcy Road, St Osyth, Clacton on Sea, Essex CO16 8QF Registered Charity Number 1125270