Surrey Heartlands Integrated Care System Area Prescribing Committee (APC)

Formulary Extension Briefing Paper

Medicine details	
Name, brand name	Liothyronine
Manufacturer	Roma Pharmaceuticals Limited
Licensed indication	• Liothyronine is indicated in adults and children for the treatment of coma of myxoedema, the management of severe chronic thyroid deficiency and hypothyroid states occurring in the treatment of thyrotoxicosis. • Liothyronine sodium can be used also in the treatment of thyrotoxicosis as an adjunct to carbimazole to prevent sub-clinical hypothyroidism developing during treatment. • Liothyronine sodium may be preferred for treating severe and acute hypothyroid states because of its rapid and more potent effect, but thyroxine sodium is normally the drug of choice for routine replacement therapy. **Note. same licensed indication as current licensed liothyronine oral option (tablets Morningside Healthcare Ltd).**
Formulation	Hard capsule (excipients: maize starch, magnesium stearate, gelatin (of possible animal origin) shell and colourings). Available in 5mcg, 10mcg and 20mcg capsules.
Usual dosage	**Adults** Starting dose of 10 or 20 micrograms every 8 hours, increasing after one week, if necessary, to the usual recommended daily dose of 60 micrograms in two or three divided doses. **Myxoedema Coma** 60 micrograms given by stomach tube, then 20 micrograms every 8 hours. It is more usual to start treatment with intravenous liothyronine. **Adjunct to carbimazole treatment of thyrotoxicosis** 20 micrograms every 8 hours. **Elderly and Paediatric population** 5 micrograms daily.

Disease and potential patient group	
Brief description of disease	Hypothyroidism is the name given to the condition resulting from an underactive thyroid gland. This means that the thyroid is not producing enough thyroid hormone for the body's needs. In very rare cases, a severe underactive thyroid may lead to a life-threatening condition called myxoedema coma.
Potential patient numbers per 100,000	The incidence rate of hypothyroidism was 226.2 per 100,000 people per year; 370 per 100,000 per year in women and 72.5 per 100,000 per year in men (NICE CKS, accessed 14/03/22). According to MMT (ePACT) system data, 224 patients received liothyronine tablets in last 12 months (to Dec 21).

SUMMARY

Reason for formulary extension

Cost saving, anticipated annual saving of £127k - max saving in one year if all tablet prescribing in primary care was replaced by capsules – based on current liothyronine tablet prescribing levels (6 months: Jun-Nov 21).
It is understood that QIPP discussions are ongoing, but if agreed by APC, it is expected that this saving would be included in the QIPP category regarding value for money / financial sustainability.

Evidence as necessary

Link to SPC: Liothyronine sodium 10 micrograms Hard Capsules - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)

According to the MHRA public assessment report, this medicine is "**bioequivalent / therapeutically equivalent** to the reference medicines, their benefits and possible side effects are considered to be the same as the reference medicines".
Therefore the capsules can be considered as interchangeable with liothyronine tablets.

Ref. page 3, 6, 10 and 11 in this MHRA public assessment report:
f3feeaf0356c02da13aa6ba5fce3011697b9812c (windows.net)
In this instance the reference medicine is Tertroxin Tablets.

Cost implications

Cost of product:

Spend on liothyronine within the CCG (primary care) for last 12 months (to Dec-21) was £278,756.
Liothyronine capsules are priced at a significant discount from the liothyronine tablets in the Drug Tariff.

	28 Tablet pack (Tariff Feb 22)	Capsule (pharma)
5mcg	£99.47	£55
10mcg	£148.00	£65
20mcg	£71.90	£55

Costing information/100,000 population and per CCG: small numbers, currently @224 patients in the CCG are using liothyronine tablets, so approx. 2 per 100,000 patients.

Availability of PAS and details (if appropriate): *No*

Availability of homecare service (if appropriate): *No*

Alternative treatments and cost per (patient per year / per month as appropriate)

Although not directly comparable, a 28-tablet pack of Levothyroxine 50 micrograms is £0.90 in Drug Tariff (Mar-22).

Impact to patients

- An oral capsule preparation that would be used instead of the tablet formulation. MHRA have noted that this product is bioequivalent to the tablets.
- This capsule formulation may not be suitable for vegetarians/vegans (gelatin).
- As per good medicine management principles, any switches in prescribing should take place in discussion with the patient (concordance).

Impact to primary care

- It is anticipated that the impact to primary care will be minimal, as APC will be advised to maintain the same criteria for initiation, maintenance and/or discontinuation as for liothyronine tablets, which itself is based on national guidance from RMOC.
- Prescribing restrictions, availability and supply will be the same as for liothyronine tablets currently.
- As per good medicine management principles, any switches in prescribing should take place in discussion with the patient (concordance).

Impact to secondary care

- It is the anticipated that the impact to secondary care will be minimal as APC will be advised to maintain the same criteria for initiation, maintenance and/or discontinuation as for liothyronine tablets, which itself is based on national guidance from RMOC.
- Trust formularies should be updated to reflect APC preferred product (in this case capsules).
- Prescribing restrictions, availability and supply will be the same as for liothyronine tablets currently.
- It is unlikely that providers will be expected to co-ordinate any mass switching programmes, perhaps an individual patient who is in on an inpatient basis. New patients should be started on liothyronine capsules only.

Impact to CCGs

- Impact to CCGs will be in the area of cost-saving, compared to current prescribing of liothyronine tablets, it is anticipated that prescribing capsules instead of tablets could make a cost-saving of £127k per annum.
- No additional payment or incentive schemes should be necessary to enable effective prescription switching.
- It should be noted that there is another opportunity to save a further £100,000 per year from deprescribing of ArmourThyroid and Erfa tablets (Black on PAD/formulary since 2016).

Implementation

- To ensure re-imbursement will either stay the same or reduce upon competition, prescriptions must be written for the appropriate strength of Liothyronine Capsules i.e. use Liothyronine Capsules (+ strength) only (no branded generic / pharma company names).
- PAD will need to be updated with new recommendation within 4 weeks of APC decision.
- To maximise possible savings, primary care prescribers and pharmacists will need to be advised of changes quickly following APC decision and assist with any switching queries or problems for patients promptly.
- Trust formularies will need to be updated with new recommendation within 4 weeks of APC decision
- Provider prescribers and pharmacists will need to be advised of changes following APC decision.

Recommendation to APC

PbRe: No

Colour classification guidelines

Recommended traffic light status (see attached guidelines):

In view of the MHRA recognition of bioequivalency of the capsules with the reference product, it is recommended that the APC apply the same traffic light statuses to the capsules as to the tablets currently, as follows.

- Coma of Myxoedema – RED
- Thyroid cancer and parathyroid cancer – RED
- Treatment resistant depression – RED
- Thyrotoxicosis – RED
- Hypothyroidism with intolerance to levothyroxine – AMBER
- Hypothyroidism with inadequate response to levothyroxine - AMBER

For those patients already being prescribed liothyronine tablets, it is recommended that prescriber contact patient to discuss switch to capsules at appropriate prescribing review, as per good medicine management practice. New patients should be initiated onto liothyronine capsules only.

Prescribers are advised to not prescribe by branded generic name/pharma company name in case another supplier enters the market).

It is recommended that traffic light status for unlicensed liothyronine preparations remains unchanged (Black/non-formulary).

Additional comments:

For consideration/noting (do not allow to divert from making decision)

1. Does PAD narrative need to be changed? Probably not, at the moment, formulation is not specified (because there was only one oral formulation at time of decision).
2. Is a dedicated switch program required for a bioequivalent product, where there are small number of patients and a relatively low level of complexity required to change prescriptions?
3. Should the PAD be proscriptive - what happens if the tariff cost for the tablets drops to the same or less than the capsules? *Note: The 10mcg tablets have remained at exactly the same price for 2 years (£148). The 5mcg tablets were also the same price for the past 2 years (£98) until Feb 22 when they increased to £99.47. The 20mcg tablets have crept down in price over the past 2 years. They are now approximately half the price that they were in Apr-Sep 2020. It is possible that the competitively priced capsules will encourage a reduction in tablet price. This remains to be seen.*

References:

1.

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Declaration of Interest:

Nil

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Declaration of Interest:

Nil

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