

General Commissioning Policy

Treatment	Armour® thyroid (thyroid tablets USP, Forrest Pharmaceuticals) and other non-UK licensed products
For the treatment of	Hypothyroidism
Background	<p>Historically, extracts of animal thyroid glands were the only way to treat thyroid under activity, but since the 1950s pure synthetic thyroid hormones have been available in tablet form of levothyroxine sodium [T4] and liothyronine [T3].</p> <p>Armour thyroid (a dried thyroid hormone extract from pigs) has been requested by patients who would like such treatment to be funded by the NHS despite the availability of UK-licensed thyroxine products.</p>
Commissioning position	NHS Hull CCG does not routinely commission the use of Armour Thyroid for the treatment of hypothyroidism.
Effective from	<p>September 2016</p> <p><i>(This policy replaces the Y&H SCG policy 17/10 dated Sept 2010)</i></p>
Summary of evidence / rationale	<p>Armour thyroid is not a licensed medicine in the UK. Licensed thyroxine preparations are available and widely prescribed.</p> <p>There is no rationale behind the use of a combination of levothyroxine and liothyronine, or of dried thyroid hormone extracts. A combination of the two, in both non- and physiological proportions, has not consistently been shown to be more beneficial than levothyroxine alone with respect to cognitive function, social functioning and wellbeing in a limited number of patients. Use of dried thyroid hormone extracts, such as Armour Thyroid, is therefore also not recommended.</p> <p>There is insufficient clinical and cost effectiveness evidence to support the use of these treatments, as explained below: (Refs 1 and 2):</p> <ul style="list-style-type: none"> • Armour thyroid contains both thyroxine (T4) and tri-iodothyronine (T3) extracted from the thyroid gland of pigs. The desiccated pig thyroid extract contains T4:T3 at a ratio of 4 to 1, whereas in humans it is 14:1. In other words, Armour thyroid extract contains excessive amounts of T3 relative to T4 when used to replace thyroid hormone in humans, which may lead to increased serum concentrations of T3 and subsequent thyrotoxic symptoms, such as palpitations and tremor. Moreover, Armour Thyroid is not a pure preparation of thyroid hormones. • Despite USA FDA regulation, there have been significant problems with the stability of Armour Thyroid in recent years, with a subsequent potential for fluctuations in thyroid hormone levels in the blood of patients treated with Armour Thyroid. These fluctuations may be unpredictable and have adverse

1. This Policy will be reviewed in the light of new evidence, or guidance from NICE.

2. General Commissioning Policies are agreed by the Planning and Commissioning Committee on behalf of NHS Hull CCG.

	<p>effects on patient's health.</p> <ul style="list-style-type: none"> • The British Thyroid Association (BTA) committee cannot recommend a treatment with possible side-effects, when a safe and equally well- established treatment exists in the form of thyroxine sodium. • Armour Thyroid is not on the British National Formulary, is not a licensed therapy in the UK and is not eligible for exemption from prescription charges for patients with a prescription charge medical exemption certificate issued for myxoedema. <p><u>Combination Thyroxine/ Tri-iodothyronine (Liothyronine) Therapy</u></p> <ul style="list-style-type: none"> • There is no currently available tablet preparation containing thyroxine and tri-iodothyronine (T4/T3) in a combination that adequately reproduces the relative quantities of these hormones produced by the human thyroid gland. Neither is there a preparation that produces a sustained release of thyroid hormones in a pattern similar to that from the human thyroid gland. • Since 1999, there have been 7 rigorously conducted RCTs, encompassing more than 900 hypothyroid patients (see refs. 5 & 6). None showed a beneficial effect of combined T4/T3 therapy on measures of wellbeing, health and mental functioning and 3 showed harmful or undesirable effects of the T4/T3 combination. • The BTA keeps an open mind about whether using an appropriate formulation of T4/T3 combination tablet would, in the future, provide benefits in the treatment of hypothyroidism for a subgroup of patients. However, based on the current evidence on currently available formulations of synthetic thyroid hormones, combined T4/T3 cannot be recommended because of a lack of benefit and a small number of undesirable and harmful treatment effects.
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References:

- 1) Armour Thyroid (USP) and combined thyroxine/ tri-iodothyronine as Thyroid Hormone Replacement. British Thyroid Association (BTA) Executive Committee - Feb 2007 http://www.british-thyroid-association.org/Guidelines/Docs/Armour_nov_07.pdf
- 2) London Medicines Information Service (2008). What is the rationale for using a combination of levothyroxine and liothyronine (such as Armour thyroid) to treat hypothyroidism? http://www.medicinesresources.nhs.uk/upload/NHSE_Armour_Thyroid_56_5final%5b1%5d.doc
- 3) FDA enforcement removed more than half a million bottles of Armour Thyroid from US pharmacies in 2005 due to unstable concentrations of thyroid hormone in the preparation. <http://www.fda.gov/Safety/Recalls/EnforcementReports/2005/ucm120349.htm>
- 4) Bunevicius R, et al. Effects of thyroxine as compared with thyroxine plus triiodothyronine in patients with hypothyroidism. N Engl J Med. 1999; 340: 424-9. <http://www.ncbi.nlm.nih.gov/pubmed/9971866>
- 5) Escobar-Morreale HF, et al. Treatment of hypothyroidism with combinations of levothyroxine plus liothyronine. J Clin Endocrin Metab. 2005; 90: 4946-54. <http://jcem.endojournals.org/content/90/8/4946.full.pdf+html>
- 6) Grozinsky-Glasberg S, et al. Thyroxine-triiodothyronine combination therapy versus thyroxine monotherapy for clinical hypothyroidism: meta-analysis of randomized controlled trials. J Clin Endocrinol Metab 2006; 91: 2592-9 <http://jcem.endojournals.org/content/91/7/2592.full.pdf+html>