AWMSG Secretariat Assessment Report – Limited submission

Triamcinolone hexacetonide 20 mg/ml suspension for injection

Company: Intrapharm Laboratories Limited

Licensed indication under consideration: Treatment of juvenile idiopathic arthritis.

Marketing authorisation date: 24 December 2013

Comparator(s)

- Imported triamcinolone hexacetonide on a named patient basis.
- Special order triamcinolone hexacetonide.
- Triamcinolone acetonide.
- Methylprednisolone acetate.

Limited submission details

- Use of triamcinolone hexacetonide for the indication under consideration is established practice and is recommended in treatment guidelines. It is expected to replace the unlicensed use of special order or imported triamcinolone hexacetonide on a named patient basis.
- Minor licence extension.
- Anticipated use in Wales is considered to have minimal budgetary impact.

Clinical effectiveness

- This submission considers a new licence extension for triamcinolone hexacetonide for treating juvenile idiopathic arthritis where previously an unlicensed product had been used.
- Triamcinolone hexacetonide is the first intra-articular corticosteroid licensed for juvenile idiopathic arthritis. Intra-articular injections of triamcinolone hexacetonide are commonly used to treat juvenile idiopathic arthritis and are recommended by UK, European and US guidelines, including the Alder Hey Hospital guidelines, British National Formulary for Children and the Standards of Care by the British Society for Paediatric and Adolescent Rheumatology. However, after the originator product Lederspan® became unavailable in the UK, triamcinolone hexacetonide had to be obtained through special order manufacturers or specialist importing on a named patient basis. The applicant company's triamcinolone hexacetonide is expected to replace the use of the unlicensed imported product.
- The Medicines and Healthcare Products Regulatory Agency (MHRA) approved triamcinolone hexacetonide for the same indications as the reference medicine Lederspan® (triamcinolone hexacetonide) although it is no longer available in the UK. Additionally, the MHRA recommended that treatment of juvenile idiopathic arthritis be added to the list of indications for triamcinolone hexacetonide.
- Triamcinolone hexacetonide was granted a hybrid licence in the UK in 2013 under the MHRA's Decentralised Procedure. The application demonstrated bioequivalence to Lederspan® 20 mg/ml suspension for injection, which already had marketing authorisation in the EU.
- Clinical expert opinion sought by AWTTC noted there is an unmet need in relation

to intra-articular use of triamcinolone hexacetonide to treat juvenile idiopathic arthritis.

- The company proposes an additional benefit of triamcinolone hexacetonide having a longer half-life than triamcinolone acetonide (Kenalog®), which would translate to two injections per year instead of three and two hospital visits instead of three.
- Common local adverse reactions associated with triamcinolone hexacetonide listed in the Summary of Product Characteristics (SPC) include sterile abscesses, post-injection erythema, pain, swelling and necrosis at the injection site. The SPC also recommends monitoring growth and development of children receiving prolonged corticosteroid treatment. No new or unexpected safety concerns arose from the MHRA's licensing procedure.

Budget impact

- The budget impact analysis is based on triamcinolone hexacetonide displacing unlicensed use of triamcinolone acetonide (Kenalog®) or methylprednisolone acetate (Depo-Medrone®). The company has not provided a budget impact analysis for triamcinolone hexacetonide displacing the imported or special order use. Calculations are based on average costs obtained by AWTTC of triamcinolone hexacetonide imported on a named patient basis.
- The company estimates an incidence of juvenile idiopathic arthritis of 735 patients per year in Wales, with 20% needing a steroid injection. The company suggests that because triamcinolone hexacetonide is the only licensed product available that all eligible patients would receive the product, resulting in 147 patients treated per year.
- Results of the budget impact analyses for triamcinolone hexacetonide versus comparators are presented in Table 1.

Table 1. Costs of triamcinolone hexacetonide for treating juvenile idiopathic arthritis

	Triamcinolone hexacetonide (Intrapharm licensed product)	Triamcinolone acetonide	Methylprednisolone acetate	Triamcinolone hexacetonide (imported on a named patient basis)
Cost per injection	£12.00	£1.49	£3.44	£18.60
Cost per hospital visit	£150.00	£150.00	£150.00	£150.00
Number of injections per year	2	3	3	2
Cost per patient per year	£324.00	£454.47	£460.32	£337.20
Number of patients	147	147	147	147
Total cost per year	£47,628.00	£66,807.09	£67,667.04	£49,568.40

- The company estimates that market uptake will remain the same in Year 1 to Year 5 which equates to a net cost saving of £19,179 for each year compared with triamcinolone acetonide and £20,039 compared with methylprednisolone acetate. There is a net cost saving of £1,940 when compared with using triamcinolone hexacetonide imported on a named patient basis using average costs obtained by AWTTC.

Additional information

- AWTTC is of the opinion that, if recommended, triamcinolone hexacetonide is appropriate for specialist only prescribing within NHS Wales for the indication under consideration.

Evidence search

Date of evidence search: 27 March 2017
Date of range of evidence search: No date limits were applied to database searches.

Further information

This assessment report will be considered for review every three years.

References are available on request. Please email AWTTC at AWTTC@Wales.nhs.uk for further information.

This report should be cited as: All Wales Therapeutics and Toxicology Centre. AWMSG Secretariat Assessment Report. Triamcinolone hexacetonide 20 mg/ml suspension for injection. Reference number: 2527. Jun 2017.