1. **Treatment & Condition**

   Adalimumab and dexamethasone for treating non-infectious uveitis.

2. **Associated appraisal body & Summary of ruling**

   NICE Technology Appraisal guidance TA460 (July 2017)

   Adalimumab is recommended as an option for treating non-infectious uveitis in the posterior segment of the eye in adults with inadequate response to corticosteroids, only if there is:
   - active disease (that is, current inflammation in the eye) and
   - inadequate response or intolerance to immunosuppressants and
   - systemic disease or both eyes are affected (or 1 eye is affected if the second eye has poor visual acuity) and
   - worsening vision with a high risk of blindness (for example, risk of blindness that is similar to that seen in people with macular oedema)

   Stop adalimumab for non-infectious uveitis in the posterior segment of the eye in adults with inadequate response to corticosteroids if there is 1 of the following:
   - new active inflammatory chorioretinal or inflammatory retinal vascular lesions, or both or
   - a 2-step increase in vitreous haze or anterior chamber cell grade or
   - worsening of best corrected visual acuity by 3 or more lines or 15 letters

   Dexamethasone intravitreal implant is recommended as an option for treating non-infectious uveitis in the posterior segment of the eye in adults, only if there is:
   - active disease (that is, current inflammation in the eye) and
   - worsening vision with a risk of blindness

3. **Number of people in Northern Ireland expected to take up service/therapy**

   The NICE guidance indicates that the eligible population size is small (around 13 people per year for adalimumab and around 11 people per year for dexamethasone). Information from local clinicians would suggest that the numbers would be slightly higher with around 20-25 patients per year for adalimumab and a similar number of patients for dexamethasone.

4. **Patient Access Scheme Availability**

   (Yes/No)

5. **Costs**

   5.1 **Drug cost per patient per annum (for new and prevalent cases)**

   **Adalimumab subcutaneous injection (Humira®)**

   The recommended dose of adalimumab for adults with non-infectious uveitis is an initial dose of 80mg, followed by 40mg every other week starting 1 week after the
initial dose. Adalimumab is given by subcutaneous injection.

Adalimumab costs £704.28 for 2 pre-filled injections

Hence, the cost per patient per annum is as follows:
- Year 1 = £9,859.92
- Year 2 and subsequent years = £9,155.64

**Dexamethasone intravitreal implant (Ozurdex®)**

The recommended dose of dexamethasone intravitreal implant is 1 implant, containing 700 micrograms of dexamethasone, to be administered intravitreally to the affected eye.

Repeat doses should be considered when a patient experiences a response to treatment followed subsequently by a loss in visual acuity and in the physician's opinion may benefit from retreatment without being exposed to significant risk. There is only very limited information on repeat dosing intervals less than 6 months.

Each dexamethasone intravitreal implant costs £870

### 5.2 Infrastructure costs Per annum

The implementation of NICE TA460 is unlikely to result in significant change in infrastructure requirements. The HSC Board will work with the Belfast Trust to identify how the requirements compare to current infrastructure needs.

### 6. Expected implementation period

There is no impediment to immediate implementation for new patients on a cost per case basis. This will allow patient numbers to be closely monitored.

### 7. Commissioning arrangements

This treatment will be formally commissioned from the Belfast Trust by the HSCB/PHA via the Specialist Services Commissioning Team. This regime will be consolidated into the commissioning arrangements in place for macular services.

### 8. Monitoring arrangements

The HSC Board will incorporate information on this regime into the existing monthly monitoring arrangements with Belfast Trust for monitoring patients with the range of macular conditions from 2018/19. This information will include:

- Number of new and review attendances
- Number of patients commenced on treatment
- Number of adalimumab intravitreal injections and dexamethasone implants administered

A monitoring report will be submitted to the Specialist Services Commissioning Team on a regular basis for formal review and comment by the team. Ongoing meetings between the HSC Board, PHA and both Trusts will continue.
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<th><strong>DoH (NI) Legislative/Policy Caveats</strong></th>
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<td>This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.</td>
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