NHS ENGLAND SPECIALISED SERVICES

CLINICAL PANEL REPORT

Date: 19 June 2019

Intervention: Maternal Intravenous Immunoglobulin (IVIg)

Indication: Prevention of alloimmune fetal and neonatal haemochromatosis (NH)

ID: 1864

Gateway: 2 (Round 1)

Programme: Women and Children

CRG: Neonatal Critical Care

Information provided to the panel

Policy Proposition

Evidence Review undertaken by Solutions for Public Health

CPAG Summary Report

1906 Urgent Policy Statement

Key elements discussed

This is policy proposition recommending for routine commissioning. This proposition was added to the work programme in October 2018 and an evidence review commissioned. However, it was discussed again at Panel in March 2019 due to regional variation in funding and IFR applications being received. The development of an urgent policy statement was agreed, whilst the evidence review was undertaken. This has now been completed and a full proposition drafted for Panel to consider.

This is a rare condition with 15 per 1 million live births, so approximately 8 or 9 per year.

The evidence review presented consisted of one large prospective case series of 151 women with a previous pregnancy affected with allo-immune NH. Women were treated with IVIg initiated at either 14 weeks or 18 weeks gestation. The study was conducted over 18 years, UK residents included. Outcomes were only recorded up to 3 months post-delivery. No evidence of long-term impact on the babies born. No cost effectiveness reported.

The Panel considered that the results reported clearly demonstrated this treatment works, although did question whether the reporting was as accurate as it could have been. Women could only be recruited to the study if they had a previous pregnancy with fetal loss or death. The Panel questioned whether this would bias this study. They could have had any number of unaffected pregnancies as well, but this information is not available.

A few minor adverse events were after the treatment injections, such as migraine. One woman developed aseptic meningitis so the treatment was stopped.

There appeared to be no difference between 14 and 18 weeks in starting treatment. The proposition is currently written as starting at 14 weeks. If the evidence shows there is no difference, then proposition needs to reflect commencement at 18 weeks. This needs to be checked with the Policy Working Group (PWG). The commissioning criteria and dosage in this proposition is in alignment with the currently published statement

The Panel ask that the PWG check the language in the proposition between maternal and fetal death to make sure it is related to babies, as not currently clear when the word ‘death’ is used on at least 3 occasions.

Recommendation

Clinical Panel recommend progressing as a for routine policy proposition, as proposed.

Why the panel made these recommendations

The evidence base is limited to one study although the Panel considered the results clearly demonstrated that this treatment works with no significant harms, even if the study was not necessarily accurately reported.

Documentation amendments required

Check with the PWG to make sure starting treatment at 18 weeks is ok. National Pharmacy Lead to approve the pharma related wording in the proposition.

Language check throughout the policy, as highlighted above.

Minor wording addition. In the flow diagram, proposition to state ‘at 14 (or 18) weeks’, not just ‘14 weeks’.

Declarations of Interest of Panel Members: None

Panel Chair: James Palmer, Medical Director

Post meeting note: During consultation it was highlighted that a previous pregnancy loss is the only way that a diagnosis of GALD would be made in the UK as there is no routine screening for this disorder in pregnancy. The proposed treatment would therefore only be offered to women in a pregnancy following fetal demise, therefore making the study findings representative of the proposed policy.