NHS ENGLAND SPECIALISED SERVICES

CLINICAL PANEL REPORT

Date: November 2021

Intervention: Rituximab

Indication: the treatment in acute thrombotic thrombocytopaenia purpura (TTP) and elective therapy to prevent TTP relapse (all ages)

URN: 2103

Gateway: 2, Round 1

Programme: Blood and Infection

CRG: Specialised Blood Disorders

Information provided to the Panel

X2 Evidence Reviews (acute and prophylactic) completed by Solutions for Public Health

Policy Proposition

Evidence to Decision Making Summary

X3 Clinical Priorities Advisory Group (CPAG) Summary reports – acute, prophylactic and a combined report

Blueteq® Form

Patient Impact Report

Equality and Health Inequalities Assessment (EHIA) Report

Policy Working Group Appendix

This Policy Proposition recommends the routine commissioning of rituximab as treatment in acute thrombotic thrombocytopaenic purpura and elective therapy to prevent TTP relapse. This is an off label use of the medicine. Rituximab has been standard of care in TTP since 2005 however commissioning responsibility was transferred to Specialised Commissioning from April 2020 as a recommendation from the Prescribed Specialised Services Advisory Group. The primary purpose of this proposition is to address inequities through mandating a standardised treatment pathway and this will be supported with a fully commissioned service and a service specification.

The evidence base supporting the proposition was presented to Panel members through evidence reviews for both acute and prophylactic use.

Within the acute evidence review, 6 studies were included. Similar mortality rates were reported in both rituximab groups and control groups. Rituximab was shown to reduce the relapse rate in people with acute TTP during the first two years after treatment but no evidence after that time period. There was no quality of life or functional outcomes information presented.

Within the elective therapy evidence review, 4 studies were included. The studies provided evidence that rituximab as an elective therapy substantially reduces the rate of relapse at up to 38 months follow-up, compared with no rituximab treatment.

It was noted that the reported dosing varied widely between the studies.

A question was raised regarding Plasma Exchange (PLEX) and the relationship with this proposition regarding the acute treatment. PLEX is known to be resource intensive and a costly treatment. PLEX was not specifically mentioned in the Population, Indication, Comparator and Outcomes (PICO) Report and hence not included in the evidence reviews.

Within the Needs Assessment section of the proposition it outlines information regarding adults however the proposition is for all ages. The treatment is licenced in adults and now has a licence in children for haematological cancers. However, this is only for 2 years and above therefore below 2 years of age should be an exclusion criterion.

EHIA – no additional comments received.

Patient Impact Report – no additional comments received.

Recommendation

Clinical Panel recommends that this proposition progresses as proposed, addressing the amendments required and with Clinical Panel Chair's sign off of those amendments.

Why the panel made these recommendations

The Panel considered that the evidence base supported the proposition.

Documentation amendments required

Policy Proposition:

- Page 4 in Current Treatments section there is a typo - 'nanobody'. This should be 'antibody'.
- Clarification required over the dosing description as currently confusing – 375mg/m2 stated in one section then 375m/2 in another.
- Page 7 - dosing also needs to be described better regarding ongoing use. Pg. 7 – a 'flat 5mg weekly' needs rewording so clear what is meant. Also, the low dose range is not specific and could be more defined.
- Page 8 - dark blue box in acute treatment pathway flow diagram – should this be rituximab plus standard of care? Needs checking.
- Page 9 – elective pathway flow diagram. Within the central triangle are 3 broad indications - the criteria need more explanation.
- Page 9 – dark blue box states start treatment urgently which seems to go against being elective. Clarification required.
- Impact on PLEX – it is plasma exchange sparing in acute episodes, but the proposition doesn't state this and so should be included.

Blueteq® form:

- The percentages used in section 1 differ to that stated in the proposition and therefore needs checking.

Declarations of Interest of Panel Members: One member who has treated patients with PLEX.

Panel Chair: Anthony Kessel, Clinical Director, National Clinical Policy Team, Specialised Services

Post Panel Note

PoC post panel note: The recommendations made by panel have been reflected within the policy proposition by the clinical fellow on 23 November 2021.