NHS ENGLAND SPECIALISED SERVICES

CLINICAL PANEL REPORT

Date: February 2021

Intervention: Abatacept

Indication: refractory idiopathic inflammatory myopathies (adults and children over 2 years old)

URN: 1925

Gateway: 2, Round 2

Programme: Internal Medicine

CRG: Specialised Rheumatology

Information provided to the Panel

Policy Proposition – clean and tracked versions

Evidence review completed by Solutions for Public Health

Clinical Panel Report – September 2020

Equality and Health Inequalities Assessment (EHIA) Report

Clinical Priorities Advisory Group (CPAG) Summary Report

Patient Impact Form

Intravenous Immunoglobulins (IVIg) Evidence Summary Table

Dept. of Health Clinical Guidelines for Immunoglobulin Use

Key elements discussed

This policy proposition recommends the routine commissioning of abatacept for refractory idiopathic inflammatory myopathies (IIM) in adults and children over the age of 2 years old. This policy proposition has been resubmitted with supplementary evidence regarding IVIg efficacy as requested by Clinical Panel when previously discussed in September 2020.

The actions and revisions requested by Panel following the last meeting were outlined and considered in turn. A few modifications were debated as still being required.

The Panel did not consider that the definition regarding the subgroups had been explicitly included in the proposition as requested, this would best define those who would benefit. This needs to be clarified as the Policy Working Group note that it has been addressed but the Panel did not consider it done. Myositis and malignancy associated myositis is not explicitly included in the proposition.

It was noted that the proposition text includes that in certain cases abatacept can be given concomitantly with IVIg however, the patient pathway diagram does not so clearly demonstrate this. It was outlined that abatacept would be used rather than IVIg when clinically appropriate but that IVIg would be given simultaneously in severe disease. The need to reduce IVIg usage is important.

Panel discussed audit requirements. The audit requirements in the proposition are stated as

mandatory – patient data to be entered into a registry. The proposition needs to state who will review this data. The proposition also states the use of a prior approval form. This was queried as to whether both were needed. If the registry is already in place then this should be used.

CPAG summary report makes factual statements regarding the low level of evidence. Committee discussion regarding the use of abatacept instead of IVIg needs to be included to ensure it is clear why the Panel's recommendation is being made.

No comments made regarding the EHIA or Patient Impact Report.

Recommendation

Clinical Panel recommends that this proposition is progressed as a for routine policy proposition.

Why the panel made these recommendations

The Panel debated the evidence base and considered the benefit of abatacept.

Documentation amendments required

Policy Proposition:

- Definition regarding the subgroups needs to be explicit – Women and Children Programme of Care Clinical Director and the Clinical Policy Team proposition lead can agree a sentence to include with PWG.
- Committee discussion to be included by the Clinical Effectiveness Team regarding the use of abatacept instead of IVIg. The policy needs to be clearer that abatacept should be used prior to IVIg and under what specific circumstances they would be started together and at what point use will be reviewed.
- Pg 9 – in the sentence relating to paediatric doses commencing with 'In patients between the ages of….' – at the of that sentence add 'by the weight-based regimen as per SmPC table'.
- Pg 9 – sentence commencing with 'This would follow a similar care pathway…' - remove as not considered to add value to the proposition.
- Pg 10 – patient pathway diagram to state more clearly abatacept can be given concomitantly.
- Pg 12 - The proposition needs to state who will review the registry data for audit purposes.
- Audit requirements – clarify if registry is already in place. If so, the reference to the prior approval system can be considered for removal from the Governance arrangements section.

Declarations of Interest of Panel Members: None received.

Panel Chair: James Palmer, Medical Director Specialised Services

Post Panel Note

The clinical panel report has been discussed with the policy working group (PWG). Each of the points have been addressed as follows:

Definition regarding the subgroups needs to be explicit – Women and Children Programme of Care Clinical Director and the Clinical Policy Team proposition lead can agree a sentence to include with PWG.

The subgroups for inclusion have been further expanded in the following statement in the 'Condition' section of the policy proposition:

'IIMs include dermatomyositis, polymyositis and juvenile dermatomyositis and excludes inclusion body myositis. The following conditions are also included in the broader remit of the policy proposition, but there is a limited evidence base; statin-induced immune-mediated necrotising myopathy due to anti-HMG-CoA reductase antibodies and dermatomyositis associated with cancer are included in the remit of this policy proposition.'

Committee discussion to be included by the Clinical Effectiveness Team regarding the use of abatacept instead of IVIg. The policy needs to be clearer that abatacept should be used prior to IVIg and under what specific circumstances they would be started together and at what point use will be reviewed.

The committee discussion has been documented in the appropriate section of the updated policy proposition by the clinical effectiveness team.

Pg 9 – in the sentence relating to paediatric doses commencing with 'In patients between the ages of….' – at the of that sentence add 'by the weight-based regimen as per SmPC table'.

This has been amended in the text.

Pg 9 – sentence commencing with 'This would follow a similar care pathway…' - remove as not considered to add value to the proposition.

This has been amended in the text.

Pg 10 – patient pathway diagram to state more clearly abatacept can be given concomitantly.

An asterisk highlighting this point has been added to the patient pathway diagram, and it has been reiterated in the main body of the text.

Pg 12 - The proposition needs to state who will review the registry data for audit purposes. Audit requirements – clarify if registry is already in place. If so, the reference to the prior approval system can be considered for removal from the Governance arrangements section.

This point was discussed with the PWG and the Head of the Clinical Policy Team. There has been no new guidance to stop using the prior approval system and therefore in line with other policies it has been retained.

The registry already exists and standardises this policy proposition with the published policy: Clinical Commissioning Policy: Rituximab for the treatment of dermatomyositis and polymyositis (adults) Reference: NHS England: 16036/P which has the same wording and feeds into the same registry.