Review for Prescribing Clinical Network

Treatment: Febuxostat for Gout

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Summary page

It has been noted that febuxostat is not currently on the Prescribing Advisory Database (PAD) despite there being a positive NICE technology appraisal (TA):

NICE TA 164 December 2008

1. Febuxostat, within its marketing authorisation, is recommended as an option for the management of chronic hyperuricaemia in gout only for people who are intolerant of allopurinol (as defined in section 2) or for whom allopurinol is contraindicated.
2. For the purposes of this guidance, intolerance of allopurinol is defined as adverse effects that are sufficiently severe to warrant its discontinuation, or to prevent full dose escalation for optimal effectiveness as appropriate within its marketing authorisation.

NICE TA 164.pdf

In order to comply with Innovation, Health & Wealth, the PAD must display how NICE guidance has been implemented for all drugs with a positive TA.

Febuxostat is licensed for the treatment of chronic hyperuricaemia in conditions where urate deposition has already occurred (including a history, or presence of, tophus and/or gouty arthritis).

- How strong is the evidence for claimed efficacy?
  (Grade A = > 1 RCT or meta-analysis; Grade B = 1 RCT or descriptive study; Grade C = expert committee report/opinion)

  Grade A – positive NICE TA

- Potential advantages in terms of: efficacy, compliance, pharmacokinetics, drug interactions and adverse effects?

For use in patients for whom the standard treatment option (allopurinol) is not appropriate as per NICE guidance above.

- Is there a clear place in therapy / treatment pathway?
  (E.g. patient type / characteristics, and relationship to other therapies)

See above

- Is monitoring for efficacy required?

Febuxostat works sufficiently quickly to allow retesting of the serum uric acid after 2 weeks. The therapeutic target is to decrease and maintain serum uric acid below 6 mg/dL (357µmol/L). Gout flare prophylaxis of at least 6 months is recommended.

- Is monitoring for toxicity required?

The most commonly reported adverse reactions in clinical trials (4,072 subjects treated at least with a dose from 10 mg to 300 mg) and post-marketing experience are gout flares, liver function abnormalities, diarrhoea, nausea, headache, rash and oedema. These adverse reactions were mostly mild or moderate in severity.

No specific monitoring for toxicity recommended in the Summary of Product Characteristics.

- Is dose titration required?

The recommended oral dose of febuxostat is 80 mg once daily without regard to food. If serum uric acid is > 6 mg/dL (357 µmol/L) after 2-4 weeks, febuxostat 120 mg once daily may be considered.

- What traffic light status is it expected to be (ie who will prescribe the drug and any restrictions required) and what is the role of the specialist / GP?

This has been discussed at the Rheumatology network with the following recommendation: It was agreed that it should be a green drug for use in line with the NICE guidance i.e. as a treatment option in patients who are intolerant of allopurinol (adverse event that is severe enough to warrant discontinuation or to prevent full dose escalation for optimal effectiveness) or for whom allopurinol is contraindicated. It was discussed that patients are often not titrated appropriately up to the maximum licensed dose of 900mg allopurinol.

- Financial implications? very small patient numbers – List price: £24.36 per month.

- National Guidance available – NICE –see above

Recommendations:

Implement as per NICE guidance with green traffic light status as recommended by the Rheumatology network.

References

NICE Technology Appraisal 164. Febuxostat for the management of hyperuricaemia in people with gout. December 2008. Available from http://guidance.nice.org.uk/TA164/QuickRefGuide/pdf/English

Summary of Product Characteristics. Adenuric. Menarini Pharma. Updated 15/01/2013. Available from: www.emc.medicines.org.uk