Committee to Evaluate Drugs (CED)

Recommendations and Reasons

Document Posted: May 2015

5-aminosalicylic acid

Product: 5-aminosalicylic acid (Pentasa®) 1 gram extended-release tablet

Class of Drugs: intestinal anti-inflammatory agent

Reason for Use: ulcerative colitis (UC) and Crohn's disease (CD)

Manufacturer: Ferring Inc.

Date of Review: September 11, 2013

CED Recommendation

The CED recommended that 5-aminosalicylic acid (Pentasa®) 1 gram extended-release tablet be funded. This new product strength for Pentasa® is equivalent, and proportionately priced, to two Pentasa® 500mg extended-release tablets.

Executive Officer Decision*

Based on the CED's recommendation, the Executive Officer decided to fund 5-aminosalicylic acid (Pentasa®) 1 gram extended-release tablet on the Ontario Drug Benefit Formulary as a General Benefit.

Funding Status*

Funded on the Ontario Drug Benefit Formulary as a General Benefit.

** This information is current as of the posting date of the document. For the most up-to-date information on Executive Officer decision and funding status, see: www.health.gov.on.ca/en/pro/programs/drugs/status_single_source_subm.aspx.*

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Highlights of Recommendation:

- Pentasa® (5-aminosalicylic acid) 1g extended-release (ER) tablet is a line-extension product. Pentasa® 500mg ER oral tablet is already listed on the Ontario Drug Benefit Formulary as a General Benefit.
- The manufacturer indicated that the 1g tablet was developed to provide patients with a high-dose Pentasa® tablet, which would help to improve patient adherence by simplifying the dosing regimen and reducing the number of tablets taken daily.
- The manufacturer's submission included a comparative dissolution study between Pentasa® 1g and 500mg ER tablets. The results of the study demonstrated that the dissolution results between Pentasa® 1g and 500mg ER tablets are equivalent. Pentasa® 1g ER tablet is proportionately formulated to Pentasa® 500mg ER tablet. Therefore, a bioequivalence study was not needed to demonstrate bioequivalence.
- As this is a line-extension submission, the efficacy and safety of Pentasa® 1g ER tablet are based on the clinical evidence established for Pentasa® 500 mg ER tablet.
- The proposed drug benefit price of Pentasa® 1g is $1.1138, which is equal to the cost of two Pentasa® 500mg ER tablets ($0.5569 per 500mg ER tablet).
- Overall, it was noted that one Pentasa® 1g ER tablet is equivalent to two Pentasa® 500mg ER tablets. Since the proposed drug benefit price for Pentasa® 1g ER tablet is equivalent to the price of two 500mg ER tablets, its budgetary impact is expected to be cost-neutral.

Background:

Inflammatory bowel diseases (IBD), such as ulcerative colitis (UC) and Crohn's disease (CD), are chronic autoimmune intestinal disorders that cause inflammation and ulceration within the gastrointestinal tract.

For Crohn's disease, 5-aminosalicylic acids (also known as 5-ASA, mesalazine or mesalamine) are typically used only to treat mild to moderate CD symptoms. "Step-up" medications such as corticosteroids, immune modifiers and biologic therapies are employed in patients with moderate to severe disease.

For ulcerative colitis, the treatment of choice is 5-ASA. Corticosteroids and immune modulators may be used to achieve symptom control in patients experiencing a flare in disease symptoms. Biologic modifiers may also be used in patients who have failed conventional therapy or in patients who are experiencing severe UC symptoms.

There are several oral 5-ASA products currently listed on the Formulary.

Detailed Discussions:

There are no additional relevant details.

Committee to Evaluate Drugs (CED)

The Committee to Evaluate Drugs (CED) is comprised of practicing physicians, pharmacists, health economists, and patient representatives. In conducting its review, the CED considers data contained in the drug manufacturer's submission, input provided by patient groups, findings from the national Common Drug Review and the pan-Canadian Oncology Drug Review, and other scientific information as necessary.

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