

**GOUT**

| <b>DRUG NAME</b> | <b>BRANDS REIMBURSED</b> | <b>DOSAGE FORM/ STRENGTH</b> | <b>REIMBURSEMENT CRITERIA</b><br>(Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)  | <b>STANDARD APPROVAL DURATION</b> |
|------------------|--------------------------|------------------------------|---|-----------------------------------|
| Febuxostat       | Uloric                   | 80 mg                        | <p><b>For the treatment of patients with documented severe allopurinol hypersensitivity syndrome* where lowering uric acid is recommended by clinical practice guidelines.</b></p> <p><b>For the treatment of patients with recurrent gout attacks despite treatment with allopurinol at a dose of 300 mg or more per day for at least six (6) months.</b></p> <p>* For the purpose of the criteria severe allopurinol hypersensitivity syndrome is defined as follows;</p> <p>The patient has had a clear exposure to allopurinol and:</p> <p>(a) at least TWO of the following major clinical criteria:</p> <ul style="list-style-type: none"> <li>(i) worsening renal function;</li> <li>(ii) acute hepatocellular injury;</li> <li>(iii) a rash including either toxic epidermal necrolysis ("TEN"), Stevens-Johnson syndrome ("SJS"), erythema multiforme, generalised maculopapular exanthem or generalized exfoliative dermatitis ("GED");</li> </ul> <p>OR</p> <p>(b) ONE of the major clinical criteria listed above and at least ONE of the following minor criteria:</p> <ul style="list-style-type: none"> <li>(i) fever</li> <li>(ii) eosinophilia</li> <li>(iii) leukocytosis.</li> </ul> <p>Note that an intolerance to allopurinol that does not meet the</p> | Initial: 1 year                   |

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|           |                   |                       | <p>above criteria will not be eligible for reimbursement.</p> <p><u>Renewals</u> will be considered in patients with objective evidence to demonstrate a benefit from treatment, documented as either a reduction in gout attacks or a reduction in uric acid levels.</p> | Renewals:<br>5 years       |