



Prior Authorization Approval Criteria

Uloric (febuxostat)

Generic name:	Febuxostat
Brand name:	Uloric
Medication class:	Xanthine oxidase inhibitor
FDA-approved use:	Chronic management of hyperuricemia in patients with gout
Available dosage forms:	40 mg and 80 mg tablets
Usual dose:	<ul style="list-style-type: none">Gout-Hyperuricemia: 40 mg orally once daily (may be increased to 80 mg once daily if serum uric acid levels are not less than 6 mg/dL after 2 weeks of therapy)Gout flare prophylaxis with an NSAID or colchicine is recommended when initiating therapy
Approximate yearly cost:	\$168.60 per month for 40 or 80 mg/day
Duration of therapy:	short term/long term

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

- Must have documented evidence of gout with hyperuricemia
- Must have tried and failed or intolerant to gout-hyperuricemia treatment with another xanthine oxidase inhibitor (i.e. allopurinol)

Criteria for continuation of therapy:

- A demonstrable decrease or cessation in gouty flares
 - A serum uric acid level less than 6 mg/dL following 2 weeks of therapy
- OR**
- A serum uric acid level greater than 6 mg/dL following 2 weeks of therapy at 40 mg daily dosing with the intent to increase to the maximum dosing of 80 mg daily

Caution:

- Use is not recommended in conditions where urate levels are greatly increased (i.e. malignancy, Lesch-Nyhan syndrome)
- Severe hepatic impairment (Child-Pugh Class C)
- Severe renal impairment (CrCl less than 30 mL/min)
- Pregnancy (Class C)

Monitoring:

- Serum uric acid levels
 - 2 weeks following initiation of therapy or a change in therapy target goal is less than 6 mg/dL
- LFT's (including transaminase) at baseline, 2 and 4 months after initiating therapy and periodically thereafter
- Symptoms of acute gouty flare

- Signs and symptoms of MI and stroke
- ADE's: abnormalities in liver enzymes, acute gouty flares, idiopathic thrombocytopenic purpura (<1%), hepatitis (<1%), immune hypersensitivity reaction (<1%), CVA or TIA (<1%), renal failure (<1%), angioedema (<1%)

Contraindication:

- Concomitant use of azathioprine (Imuran, Azasan)
- Concomitant use of mercaptopurine (Purinethol)
- Concomitant use of theophylline (Elixophyllin, Theo-24, Uniphyl, etc.)
- Less than 18 years of age (safety and efficacy not established in pediatric populations)

Not approved if:

- Patient does not meet criteria for use or for continuation of therapy
- Patient is taking medications that are contraindicated as listed above
- Patient is less than 18 years of age

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 06/10/09