SmartPA Criteria Proposal

Drug/Drug Class:	Antihyperuricemic Agents PDL Edit
First Implementation Date:	June 21, 2011
Proposed Date:	June 18, 2020
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: Hyperuricemia, defined as serum uric acid greater than 6.8mg/dL, can occur either due to an overproduction of uric acid, an under excretion of uric acid, or a combination of the two mechanisms. Most often, hyperuricemia results as a reduction in fractional clearance of urate rather than an over production of urate, occurring as a result of primary hyperuricemia and secondary hyperuricemia. Hyperuricemia is the most important risk factor for developing gout. Gout is the crystal deposition of monosodium urate associated with elevated levels of uric acid. Crystals are deposited in joints, tendons, and surrounding tissues. Some clinical manifestations of gout may include recurrent flares of inflammatory arthritis (gout flare), chronic arthropathy, accumulation of urate crystals in the form of tophaceous deposits, and uric acid nephrolithiasis. Acute attacks of gout are painful and over half of all cases involve the metatarsophalangeal joint of the great toe. Treatment of gout is divided into two phases: acute treatment and chronic prevention. Acute gouty arthritis can be treated with colchicine, NSAIDs, and corticosteroid injections. Urate-lowering agents are uricosuric drugs or xanthine oxidase inhibitors have shown results in reduced frequency of progression of gout to the tophaceous stage. Evidence-based recommendations for the treatment of gout address symptomatic control of acute gout, urate lowering therapy, and prophylaxis of acute attacks. It is recommended to screen patients who are of Chinese, Thai, Korean or other ethnicities who have an increased frequency of the human leukocyte antigen (HLA)-B*5801 gene as giving them allopurinol is associated with an increased risk of severe cutaneous adverse reaction (SCAR), so it is not recommended. Allopurinol and febuxostat are both not recommended in patients who are also taking azathioprine or 6-mercaptopurine, patients with urolithiasis, and those who have a risk of uric acid nephropathy.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Allopurinol • Mitigare® • Probenecid • Probenecid/Colchicine	• Colchicine • Colcrys® • **Febuxostat** • **Gloperba®** • Uloric® • Zyloprim®

Type of Criteria:	☐ **Increased risk of ADE**	☒ **Preferred Drug List**
	☐ **Appropriate Indications**	☐ **Clinical Edit**
Data Sources:	☐ **Only Administrative Databases**	☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Antihyperuricemic Agents
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 1 or more preferred agents
  - Documented trial period of preferred agents **OR**
  - Documented ADE/ADR to preferred agents **AND**
- For non-preferred colchicine products: documented reason why brand Mitigare is not appropriate **OR**
- For Uloric: adequate therapeutic trial of allopurinol defined as 60 days of therapy in the last 90 days

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if no approval criteria are met

Required Documentation

Laboratory Results:	☐	Progress Notes:	☐
MedWatch Form:	☐	Other:	☐

Disposition of Edit

Denial: Exception Code “0160” (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

1. Evidence-Based Medicine and Fiscal Analysis: “Antihyperuricemic Agents - Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; May 2020.
2. Evidence-Based Medicine Analysis: “Antihyperuricemics”, UMKC-DIC; March 2020.
3. Zyloprim [package insert]. East Brunswick, NJ: Casper Pharma; 2018.
4. Colcrys [package insert]. Deerfield, IL: Takeda; 2015.
5. Mitigare [package insert]. Memphis, TN: Hikma Americas, Inc.; 2019.
6. Gloperba [package insert]. Alpharetta, GA: Avion Pharmaceuticals, LLC; 2019.
7. Uloric [package insert]. Deerfield, IL: Takeda Pharmaceuticals America; 2019.
8. Probenecid [package insert]. Parsippany, NJ: Actavis Pharma, Inc.; 2016.
9. Probenecid and colchicine [package insert]. Fairfield, NJ: Ingenus Pharmaceuticals NJ, LLC; 2018.
10. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
11. USPDI, Micromedex; 2020.
12. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.
13. Gaffo, A. (2019). Clinical manifestations and diagnosis of gout. In P.L. Romain (Ed.), *UpToDate*.
14. Becker, M., & Perez-Ruiz, F. (2020). Pharmacologic urate-lowering therapy and treatment of tophi in patients with gout. In P.L. Romain (Ed.), *UpToDate.*