

SmartPA Criteria Proposal

Drug/Drug Class:	Thrombocytopenia Agents PDL Edit
First Implementation Date:	April 4, 2019
Proposed Date:	June 17, 2021
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	<input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

Executive Summary

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

Why Issue Selected: The agents for thrombocytopenia vary in their mechanism of action, but all agents in this class increase platelet count. The approved indications vary among agents. Romiplostim, eltrombopag, fostamatinib, and avatrombopag are approved for the treatment of chronic immune thrombocytopenia (ITP) in adults (and children ≥ 1 year for eltrombopag and romiplostim) after insufficient response to corticosteroids, immunoglobulins, or splenectomy. Avatrombopag and lusutrombopag are approved for short-term use (5 to 7 days) in patients with chronic liver disease who are scheduled to undergo a procedure. Eltrombopag is also approved in patients with thrombocytopenia who require interferon-based therapy for hepatitis C and patients with severe aplastic anemia. These agents have not been directly compared to each other.

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

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"> NPlate[®] Promacta[®] 	<ul style="list-style-type: none"> Doptelet[®] Mulpleta[®] Tavalisse[®]

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: Thrombocytopenia Agents
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- For documented diagnosis of chronic immune thrombocytopenia:
 - Approvable agents: Doptelet, NPlate, Promacta, or Tavalisse **AND**
 - Adequate therapeutic trial of a corticosteroid (defined as 30 out of 60 days) **AND**
 - For Tavalisse or Doptelet:
 - Participants aged 18 years or older **AND**
 - Failure to achieve desired therapeutic outcomes with trial on 2 preferred agents **OR**
 - Documented ADE/ADR to preferred agents
- For documented diagnosis of short-term use (5-7 days) in participants with chronic liver disease who are scheduled to undergo a procedure:
 - Approvable agents: Doptelet or Mulpleta

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

Required Documentation

Laboratory Results:
MedWatch Form:

Progress Notes:
Other:

Disposition of Edit

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

Default Approval Period

1 year

References

1. USPDI, Micromedex; 2021.
2. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.
3. Evidence-Based Medicine and Fiscal Analysis: "Agents for Thrombocytopenia – Therapeutic Class Review", Conduent, L.L.C., Richmond, VA; June 2021.
4. Evidence-Based Medicine Analysis: "Thrombocytopenia Treatment Agents", UMKC-DIC; May 2021.
5. Doptelet [package insert]. Durham, NC: AkaRx, Inc., October 2020.
6. Mulpleta [package insert]. Shionogi Inc; April 2020.
7. Nplate [package insert]. Florham Park NJ: Thousand Oaks, CA: Amgen Inc., February 2021.
8. Promacta [package insert]. East Hanover NJ: Novartis Pharmaceuticals Corporation; February 2021.