

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Thrombocytopenia Agents PDL Edit
<b>First Implementation Date:</b>	April 4, 2019
<b>Proposed Date:</b>	September 15, 2022
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<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  $\geq 1$  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"> <li>NPlate<sup>®</sup></li> <li>Promacta<sup>®</sup></li> </ul>	<ul style="list-style-type: none"> <li>Doptelet<sup>®</sup></li> <li>Mulpleta<sup>®</sup></li> <li>Tavalisse<sup>®</sup></li> </ul>

**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

- Evidence-Based Medicine Analysis: "Thrombocytopenia Treatment Agents", UMKC-DIC; June 2022.
- Evidence-Based Medicine and Fiscal Analysis: "Agents for Thrombocytopenia – Therapeutic Class Review", Conduent, L.L.C., Richmond, VA; June 2021.
- Doptelet [package insert]. Durham, NC: AkaRx, Inc., July 2021.
- Mulpleta [package insert]. Shionogi Inc; April 2020.
- Nplate [package insert]. Florham Park NJ: Thousand Oaks, CA: Amgen Inc., February 2022.
- Promacta [package insert]. East Hanover NJ: Novartis Pharmaceuticals Corporation; October 2021.
- Tavalisse [package insert]. South San Francisco, CA: Rigel Pharmaceuticals, Inc; November 2020.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.