Drug Policy:
Ojjaara™ (momelotinib)

POLICY NUMBER UM ONC_1488	SUBJECT Ojjaara™ (momelotinib)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 11/08/23, 11/13/24	APPROVAL DATE November 13, 2024	EFFECTIVE DATE November 29, 2024	COMMITTEE APPROVAL DATES 11/08/23, 11/13/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Evolent Specialty Services Clinical Guideline Review Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Ojjaara (momelotinib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided:

1. The member has not experienced disease progression on the requested medication AND
2. The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
3. Additional medication(s) are not being added to the continuation request.

B. Myelofibrosis

1. Ojjaara (momelotinib) may be used for the treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [post-polycythemia vera (PV) and post-essential thrombocythemia (ET)], in adult members with anemia.
2. Evolent policy supports use of Ojjaara (momelotinib) for myelofibrosis (MF) if all of the following criteria are met:

a. Members have intermediate or high-risk MF
b. Members have failed, are intolerant, or have a contraindication to Jakafi (ruxolitinib)
    i. Presence of anemia is not a contraindication for use with Jakafi (ruxolitinib)
    ii. Starting dose of Jakafi (ruxolitinib) is based on platelet count; consider maximum of 10 mg twice daily for 12 weeks before escalating dose in patients with baseline anemia
c. Members have a hemoglobin (HgB) level less than 10 g/dL

III. EXCLUSION CRITERIA

A. Disease progression while taking Ojjaara (momelotinib).

B. Concurrent use with other anticancer therapies.

C. Dosing exceeds single dose limit of Ojjaara (momelotinib) 200 mg.

D. Treatment exceeds the maximum limit of 30 (100 mg), 30 (150 mg), and 30 (200 mg) tablets/month.

E. Investigational use of Ojjaara (momelotinib) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Ojjaara prescribing information 2023. GlaxoSmithKline, Durham, NC

B. Verstovsek S, et al. Momelotinib versus danazol in symptomatic patients with anemia and myelofibrosis (MOMENTUM): results from an international, double-blind, randomized, controlled, phase 3 study. The Lancet 2023; 401: 269-80. DOI: https://doi.org/10.1016/S0140-6736(22)02036-0

C. Mesa R, et al. SIMPLIFY-1: A Phase III Randomized Trial of Momelotinib Versus Ruxolitinib in Janus Kinase Inhibitor-Naïve Patients with Myelofibrosis. J Clin Oncol 2017; 35 (34): 3844-3850. DOI: 10.1200/JCO.2017.73.4418

D. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs Bethesda, MD 2024.

E. Clinical Pharmacology Elsevier Gold Standard 2024.

F. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2024.

G. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2024.

H. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

I. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.