

POLICY NUMBER UM_ONC_1315	SUBJECT Rydapt™ (midostaurin)	DEPT/PROGRAM UM Dept	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 05/04/17, 05/07/18, 07/10/19, 12/11/19, 07/08/20	APPROVAL DATE July 8, 2020	EFFECTIVE DATE July 31, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 05/04/17, 05/07/18, 07/10/19, 12/11/19, 07/08/20
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler	COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 1	NCQA STANDARDS UM 2	ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS	APPLICABLE LINES OF BUSINESS All	

I. PURPOSE

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

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century 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

1. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

- When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**
- When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**
- For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies **AND**
- Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
- When available, generic drug alternatives are preferred over Brand name drugs.

2. Acute Myelogenous Leukemia (AML)

- The member has documented FLT3 mutation-positive AML (ITD and/or TKD mutations) as detected by an FDA approved test e.g. the LeukoStrat CDx FLT3 Mutation Assay **AND**
- Rydapt (midostaurin) is being used in **ANY** of the following:
 - For treatment induction/initial treatment in combination with standard chemotherapy (e.g. cytarabine and daunorubicin/idarubicin) **OR**



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- ii. For post-remission/consolidation therapy in combination with cytarabine following complete response to previous induction/initial therapy.

3. Systemic Mastocytosis

- a. The member has aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL) and Rydapt (midostaurin) will be used as a single agent.

III. EXCLUSION CRITERIA

1. Disease progression on Rydapt (midostaurin) or another FLT-3 inhibitor, e.g. Xospata (gilteritinib).
2. Dosing exceeds single dose limit of Rydapt (midostaurin) 100 mg.
3. Treatment exceeds the maximum limit of 240 (25 mg) tablets/month.
4. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

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

V. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Rydapt PI prescribing information. Novartis Pharmaceuticals Corporation. East Hanover, New Jersey 2020.
2. Clinical Pharmacology Elsevier Gold Standard. 20120
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.