Drug Policy:

Generic Drugs

POLICY NUMBER UM ONC_1304	**SUBJECT** Generic Drugs		**DEPT/PROGRAM** UM Dept	**PAGE 1 of 8**
DATES COMMITTEE REVIEWED 02/08/17, 02/14/18, 02/13/19, 05/28/19, 06/12/19, 07/10/19, 09/11/19, 12/11/19, 02/12/20, 05/13/20, 08/12/20, 11/11/20, 04/14/21, 06/09/21, 10/13/21, 11/15/21, 03/09/22, 05/11/22, 01/11/23, 03/08/23, 03/13/24	**APPROVAL DATE** March 13, 2024	**EFFECTIVE DATE** March 29, 2024	**COMMITTEE APPROVAL DATES** 02/08/17, 02/14/18, 02/13/19, 05/28/19, 06/12/19, 07/10/19, 09/11/19, 12/11/19, 02/12/20, 05/13/20, 08/12/20, 11/11/20, 04/14/21, 06/09/21, 10/13/21, 11/15/21, 03/09/22, 05/11/22, 01/11/23, 03/08/23, 03/13/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management 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 generic drugs usage in the treatment of cancer. Generic drug list is also being used to identify drugs with which Evolent has no policies and are reviewed based on CMS approved compendia criteria.

Initial Clinical Reviewers will review the request to determine if the request meets standards for medical necessity and issue a determination. If a determination is not rendered, the Initial Clinical Reviewer will escalate the treatment request to a Physician Peer Clinical Reviewer. All requests will be reviewed within the contractual timeframe.

II. DEFINITIONS

A. Generic Drugs: A generic drug is identical-or bioequivalent-to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.

1. To gain FDA approval, a generic drug must meet all the following criteria:
    a. Contain the same active ingredients as the innovator drug (inactive ingredients may vary)
    b. Be identical in strength, dosage form, and route of administration
    c. Have the same use indications
    d. Be bioequivalent
    e. Meet the same batch requirements for identity, strength, purity, and quality
    f. Be manufactured under the same strict standards of FDA’s good manufacturing practice regulations required for innovator products.

B. Drugs that the FDA considers to be therapeutically equivalent to other pharmaceutically equivalent products, i.e., drug products for which:

1. There are no known or suspected bioequivalence problems. These are designated AA, AN, AO, AP, or AT, depending upon the dosage form; or
2. Actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence supporting bioequivalence. These are designated AB.

C. Drug products that the FDA currently considers not to be therapeutically equivalent to other pharmaceutically equivalent products, i.e., drug products for which actual or potential bioequivalence problems have not been resolved by adequate evidence of bioequivalence:

1. Often the problem is with specific dosage forms rather than the active ingredients.
2. These are designated BC, BD, BE, BN, BP, BR, BS, BT, BX, or B*.

III. POLICY

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. Treatment request outside the approved FDA manufacturer labeling or CMS approved compendia must follow CMS Medicare Benefit Policy Manual Chapter 15. If references are not produced, delays may occur to the processing of such request.

A. Inclusion Criteria: For all drugs found under *Attachment A*, Evolent will be following Compendia for updates (National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Clinical Pharmacology, Lexi-Drugs, Micromedex, and AHFS Drug Information) for dosing, indications/inclusion criteria, and monitoring.

1. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:
    a. 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
    b. 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
    c. For Health Plans that utilize Evolent UM Oncology Clinical Policies, and there is no Health Plan PDL applicable, the Preferred Drug Guidelines shall follow Evolent recommended agents/regimens/preferred drugs AND
    d. Continuation requests of previously approved non-preferred medication are not subject to this provision AND
    e. When applicable, generic alternatives are preferred over brand-name drugs AND
    f. When there is a documented drug shortage, disease progression, contraindication, or confirmed intolerance to a preferred drug/regimen, per Evolent Policy and Pathway, the available alternative product may be used if deemed medically appropriate and the indication is listed in a standard reference compendium or accepted peer review literature. For a list of current drug shortages, please refer to FDA drug shortage website in the reference section.

B. Exclusion Criteria: The drugs found in *Attachment A* is not considered medically necessary when any of the following selection criteria is met:

1. Request for Name Brand product when a generic alternative is available.
2. Disease progression while receiving the same drug/regimen containing the same drug.
3. Investigational use of generic drugs 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:
    a. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
    b. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
    c. 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.
    d. 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).
    e. 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.
    f. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
    g. 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.
4. Used in members with high grade adverse effects/toxicity due to the drug.

IV. PROCEDURE

For all drugs found under Attachment A, Evolent will be following Compendia for updates (National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Clinical Pharmacology, Lexi-Drugs, Micromedex and AHFS Drug Information) for dosing, indications/inclusion criteria, and monitoring.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. Attachment A: List of Drugs

B. Attachment B: Summary of FDA’s Orange Book Therapeutic Equivalence Code

VII. REFERENCES

A. Clinical Pharmacology Elsevier Gold Standard 2023.

B. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2023.

C. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2023.

D. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs Bethesda, MD 2023.

E. FDA Approved drug products with therapeutic equivalence evaluation. 42nd edition. Orange book: https://www.fda.gov/media/71474/download .

F. 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.

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

H. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

Attachment A: List of Drugs

Brand Name	Generic Name
ADRIAMYCIN	DOXORUBICIN
ADRUCIL	FLUOROURACIL
AFINITOR	EVEROLIMUS
ALKERAN	MELPHALAN
ARIMIDEX	ANASTROZOLE
AROMASIN	EXEMESTANE
ARRANON	NELARABINE
BICNU	CARMUSTINE
BLENOXANE	BLEOMYCIN
BUSULFEX	BUSULFAN
CAMPTOSAR	IRINOTECAN
CASODEX	BICALUTAMIDE
CEENU/GLEOSTINE	LOMUSTINE
CERUBIDINE	DAUNORUBICIN
COSMEGEN	DACTINOMYCIN
CYTOSAR-U	CYTARABINE
CYTOXAN	CYCLOPHOSPHAMIDE
DACOGEN	DECITABINE
DTIC-DOME	DACARBAZINE
ELLENCE	EPIRUBICIN
ELOXATIN	OXALIPLATIN
EMCYT	ESTRAMUSTINE
EULEXIN	FLUTAMIDE
EVISTA	RALOXIFENE
EXJADE	DEFERASIROX
FARESTON	TOREMIFENE
FASLODEX	FULVESTRANT
FEMARA	LETROZOLE
FLUDARA	FLUDARABINE
FOLOTYN	PRALATREXATE
FUDR	FLOXURIDINE
Brand Name	**Generic Name**

GEMZAR	GEMCITABINE
GLEEVEC	IMATINIB
HYCAMTIN	TOPOTECAN
HYDREA/SIKLOS	HYDROXYUREA
IDAMYCIN	IDARUBICIN
IFEX	IFOSFAMIDE
INFUGEM	GEMCITABINE
JADENU	DEFERASIROX
LEUCOVORIN	LEUCOVORIN
LEUKERAN	CHLORAMBUCIL
LEUSTATIN	CLADRIBINE
LYSODREN	MITOTANE
MATULANE	PROCARBAZINE
MESNEX	MESNA
UVADEX	METHOXSALEN
METHOTREXATE	METHOTREXATE
MUTAMYCIN	MITOMYCIN
MYLERAN	BUSULFAN
NAVELBINE	VINORELBINE
NILANDRON	NILUTAMIDE
NIPENT	PENTOSTATIN
NIZORAL	KETOCONAZOLE
NOLVADEX	TAMOXIFEN
NOVANTRONE	MITOXANTRONE
ONCOVIN	VINCRISTINE
PARAPLATIN	CARBOPLATIN
PLATINOL	CISPLATIN
PURINETHOL/PURIXAN	MERCAPTOPURINE
SORIATANE	ACITRETIN
SUTENT	SUNITINIB
SYLATRON/PEGINTRON	PEGINTERFERON ALFA-2B
TABLOID	THIOGUANINE
TAXOL	PACLITAXEL
TAXOTERE	DOCETAXEL
Brand Name	**Generic Name**

TEMODAR	TEMOZOLOMIDE
TEPADINA	THIOTEPA
TICE	BCG
TOPOSAR	ETOPOSIDE
TRISENOX	ARSENIC TRIOXIDE
TYKERB	LAPATINIB
VELCADE	BORTEZOMIB
VELBAN	VINBLASTINE
VIDAZA	AZACITIDINE
ONCOVIN	VINCRISTINE
XELODA	CAPECITABINE

Attachment B: Summary of FDA's Orange Book Therapeutic Equivalence Code

Code	Interpretation
AA	No bioequivalence problems in conventional dosage forms
AB	Meets necessary bioequivalence requirements
AB1	Meets bioequivalence requirements to AB1 rated reference drug
AB2	Meets bioequivalence requirements to AB2 rated reference drug
AB3	Meets bioequivalence requirements to AB3 rated reference drug
AB4	Meets bioequivalence requirements to AB4 rated reference drug
AN	Solution or powder for aerosolization
AO	Injectable oil solutions
AP	Injectable aqueous solutions
AT	Topical Products
BC	Controlled-release tablet, capsule, or injectable
BD	Documented bioequivalence problems
BE	Enteric coated oral dosage forms
BN	Product in aerosol-nebulizer delivery system
BP	Potential bioequivalence problems
BR	Suppository or enema for systemic use
BS	Testing standards are insufficient for determination
BT	Topical products with bioequivalence issues
BX	Insufficient data to confirm bioequivalence
B*	Requires further FDA investigation and review
EE	This entry has been evaluated by the FDA, but a rating is not available for this labeler's product
ZZ	FDA standard with no orange book code