Drug Policy:

Generic Drugs

POLICY NUMBER UM ONC_1304	**SUBJECT** Generic Drugs		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 6**
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	**APPROVAL DATE** August 12, 2020	**EFFECTIVE DATE** August 28, 2020	**COMMITTEE APPROVAL DATES** (latest version listed last) 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	
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** 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 New Century Health (NCH) 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

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.

To gain FDA approval, a generic drug must:

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

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

A. There are no known or suspected bioequivalence problems. These are designated AA, AN, AO, AP, or AT, depending upon the dosage form; or

B. Actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence supporting bioequivalence. These are designated AB.

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

III. POLICY

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

Inclusion Criteria: For all drugs found under *Attachment A*, New Century Health 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.

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. 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
2. 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
3. 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
4. Continuation requests of previously approved non-preferred medication are not subject to this provision AND
5. When available, generic alternatives are preferred over brand-name drugs.

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

A. Disease progression while receiving the same drug/regimen containing the same drug

B. Indications and dosing are not supported by CMS recognized compendia or acceptable peer reviewed literature.

C. Used in members with high grade adverse effects/toxicity due to the drug.

IV. PROCEDURE

Requests for drugs in Attachment A shall be reviewed for appropriateness per FDA approved product labeling, the National Comprehensive Cancer Network (NCCN) and American Society of Clinical Oncology (ASCO) clinical guidelines, or CMS approved compendia.

Dosage and Administration/Dosage Adjustments/Monitoring:

For all drugs found under attachment A, New Century Health 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. 2020.

B. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.

C. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.

D. AHFS Drug Information. American Society of Health-Systems Pharmacists. Bethesda, MD. 2020.

E. Lexicomp. Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc. 2020.

F. FDA (2020) Approved drug products and therapeutic equivalence evaluation. (38th edn), Orange book preface, FDA, USA.

Attachment A: List of Drugs

Brand Name	Generic Name
ADRIAMYCIN	DOXORUBICIN
ADRUCIL	FLUOROURACIL
ALKERAN	MELPHALAN
ARIMIDEX	ANASTROZOLE
AROMASIN	EXEMESTANE
BACILLUS CALMETTE-GUERIN	BCG
BICNU	CARMUSTINE
BLENOXANE	BLEOMYCIN
BUSULFEX	BUSULFAN
CAMPTOSAR	IRINOTECAN
CASODEX	BICALUTAMIDE
CEENU	LOMUSTINE/GLEOSTINE
CERUBIDINE	DAUNORUBICIN
COSMEGEN	DACTINOMYCIN
CYTOSAR-U	CYTARABINE
CYTOXAN	CYCLOPHOSPHAMIDE
DACOGEN	DECITABINE
DTIC-DOME	DACARBAZINE
ELLENCE	EPIRUBICIN
ELOXATIN	OXALIPLATIN
EMCYT	ESTRAMUSTINE
EULEXIN	FLUTAMIDE
EVISTA	RALOXIFENE
EVOMELA	MELPHALAN CAPTISOL ENABLED
FARESTON	TOREMIFENE
FEMARA	LETROZOLE
FLUDARA	FLUDARABINE
FUDR	FLOXURIDINE
GEMZAR	GEMCITABINE
HALOTESTIN	FLUOXYMESTERONE
HYCAMTIN	TOPOTECAN
HYDREA	HYDROXYUREA

IDAMYCIN	IDARUBICIN
IFEX	IFOSFAMIDE
JADENU	DEFERASIROX
KEPIVANCE	PALIFERMIN
LEUCOVORIN	LEUCOVORIN
LEUKERAN	CHLORAMBUCIL
LEUSTATIN	CLADRIBINE
LYSODREN	MITOTANE
MATULANE	PROCARBAZINE
PURINETHOL/PURIXAN	MERCAPTOPURINE
MESNEX	MESNA
METHOXSALEN	UVADEX
METHOTREXATE	METHOTREXATE
MUSTARGEN	MECHLORETHAMINE
MUTAMYCIN	MITOMYCIN
MYLERAN	BUSULFAN
NAVELBINE	VINORELBINE
NILANDRON	NILUTAMIDE
NIPENT	PENTOSTATIN
NIZORAL	KETOCONAZOLE
NOLVADEX	TAMOXIFEN
NOVANTRONE	MITOXANTRONE

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