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Medical office update

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In this issue

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Generic vs Brand Drugs: What's the Difference?

Patients and healthcare professionals alike often eagerly anticipate the availability of generic medications, which are found to be just as safe and effective as their branded counterparts, and generally more affordable. The Food and Drug Administration (FDA) defines a generic drug as "identical, or bioequivalent, to a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use." [1]

For medications to be deemed an AB-rated generic, both pharmaceutical and bioequivalence to the brand counterpart must be proven. "Pharmaceutical equivalence" means the generic medication must have the same active ingredient(s), dosage form, route of administration, and strength or concentration as its branded counterpart. AB-rated generic equivalents are regarded as

interchangeable.

"Bioequivalence" requires the drug be comparable in bioavailability — its rate and extent of absorption — under similar conditions. [2] The bioavailability of most generics differ from their branded counterparts by less than four percent. [3] The process to determine if a generic drug is bioequivalent to its branded counterpart is the same process that is used to prove a new formulation of a drug (e.g. an oral solution) is the same as the original formulation (e.g. an oral capsule). This process is also used to compare different batches of the same drug to one another, ensuring consistency of the product throughout production. [4]

Generic medications, being evaluated in this same manner, provide safe, effective, and generally more affordable alternatives to branded medications; thus, improving medication value in the healthcare system.

The Orange Book is a tool to help determine whether a generic drug is therapeutically equivalent to a branded medication. Please reference *The Orange Book* for coding to determine if products are therapeutically equivalent. [5]

References

1. Food and Drug Administration, Center for Drug Evaluation and Research. Generic Drugs: Questions & Answers? June 1, 2018. **https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers#q1** (Accessed December 7, 2019).
2. Approved drug products with therapeutic equivalence evaluations. 39th Edition. Federal Food and Drug Administration. 2019. **https://wayback.archive-it.org/7993/20190214030105/https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm071436.pdf** (Accessed December 7, 2019).
3. Davit BM, Nwakama PE, Buehler GJ, et al. Comparing generic and innovator drugs: a review of 12 years of bioequivalence data from the United States Food and Drug Administration. Ann Pharmacother. 2009;43:1583-1597.
4. Food and Drug Administration, Center for Drug Evaluation and Research. FDA Ensures Equivalence of Generic Drugs. August 21, 2015.

Medical necessity policy updates

We've recently updated our medical necessity criteria. You can find the following changes at our **medical necessity criteria page** .

Breast reconstruction surgery after mastectomy or lumpectomy
Cochlear implants and auditory brainstem implants
Custom compression garments
Hospital beds
Mammography adjunct technology - Criteria no longer in use, policy retired
Obstructive sleep apnea non-surgical treatment
Serum antibodies for diagnosis of inflammatory bowel disease
Standing frames

Injectable medication updates

The following prior authorization updates have been made to the injectable medications currently in the MagellanRX program. Magellan Rx will review all prior authorization requests for these specialty injectable medications, along with other specialty medications that are already part of the program when administered in:

- An outpatient facility
- A patient's home

A physician's office

Policy Changes

Effective March 10, 2020

- Herceptin (J9355): Removed CNS cancer as a covered indication
- Ixempra (J9207): To metastatic or recurrent HER2-negative disease, added use is after prior treatment with an anthracycline or a taxane
- Kadcyla (J9354):
  - Breast Cancer: To adjuvant therapy, removed use for locally advanced disease following completion of planned chemotherapy if residual disease after preoperative therapy.
  - NSCLC: Added patient must have adenocarcinoma histology.
- Perjeta (J9306): Breast cancer
  - To adjuvant treatment for breast cancer, added patient must have node-positive (N1-N3) disease.
  - To neoadjuvant treatment, added patient must have tumor size > 2 cm diameter (T2-T4d) or node-positive (N1-N3) disease.
- Bortezomib (J9044): See Velcade updates below
- Bavencio (J9023):
  - Merkel Cell Carcinoma: Added patient must have 'disseminated' metastatic disease and added patient must not have local or regional disease.
  - Renal Cell Carcinoma: Restricted use to patients with clear cell histology for advanced or metastatic disease.
- Darzalex (J9145): For multiple myeloma, removed use in combination with pomalidomide and dexamethasone
- Velcade (J9041):
  - Systemic Light Chain Amyloidosis: To newly diagnosed disease, removed use as a single agent and in combination with dexamethasone without melphalan.
  - Waldenström's macroglobulinemia/Lymphoplasmacytic Lymphoma: To use in combination with dexamethasone and rituximab, restricted use to primary therapy.
  - Multicentric Castleman's Disease: Removed indication along with corresponding ICD-10 codes (D36.0, R59.0, R59.1, R59.9, D47.Z2).
  - Adult T-Cell Leukemia/Lymphoma: Removed indication along with corresponding ICD-10 codes (C91.50, C91.52).
  - Pediatric Acute Lymphoblastic Leukemia: To relapsed or refractory Philadelphia chromosome positive disease, removed use in combination with dasatinib or imatinib to only allow use as a component of the COG AALL07P1 regimen.
- Vyxeos (J9153): For therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC), restricted use to patients at least 60 years of age or older

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