

Disclaimer and Update Policy

Every attempt is made to ensure that the data in ACCC's Oncology Drug Database is timely and accurate. However, there will be instances for some data items where there is a lag between the time when a change occurs (for example, the date of approval of a new cancer drug) and when that change is reflected in the database (continuing with the example, the date when the new drug gets listed). Shown below are two lists. The first identifies the data items for which there should not be any lag—either because the information does not change (for example, a drug's generic name) or because the information is available early enough to allow its inclusion in the database before it becomes effective (for example, Medicare payment limits). The second list focuses on data elements for which a lag is possible. If you have questions about this disclaimer and update policy, please email: drugdatabase@acc-cancer.org

Data Items That are Current as of Access Date

- Drug names (brand and generic)
- Dosage Form
- Package
- Strength
- Type of Drug
- Year Introduced
- Payment Category (whether paid under Part B or Part D)
- HCPCS
- Medicare Payment Limit (**does not include the reduction due to sequestration**)
- Labeler
- Payment Category

Data Items with Potential Lag Time

- List of cancer-related drugs
 - Newly approved drugs that qualify for inclusion (that is, that are relevant for treating cancer or for supportive care of cancer patients) will be added to the list within 5 (business) days of approval. In light of the fact that more time than that is likely to elapse before the drug is commercially available, this lag will not have implications for site users.
 - There may be instances in which drugs are withdrawn from the market. These drugs will be deleted from the dataset within 1 month of the announced withdrawal. The resultant lag means that some information will be retained in the database for a short time after its relevance. However, this will not impact users as they will no longer be using this information.
- List of all active NDC numbers for any drugs. New NDC numbers are frequently issued for marketed drugs because any change in the drug itself (for example, new coloring for a tablet) or in the way it is packaged (replacing a glass bottle with a plastic one) will generate the need for a new code. In addition, active NDC numbers can also become inactive.

There is no central listing of newly issued NDCs. As a result, there will be some lag in the time between when a new NDC number is issued and when it will be entered into the database. Similarly, when an NDC number becomes inactive there will also be some lag time before this number is removed from the database. Because NDCs will be reviewed on a monthly basis, that lag time in either instance will not exceed 4 weeks. The date of completion for the most recent review appears in the NDC table (in the column heading for active NDCs).

- FDA-approved indication(s). Manufacturers can request additions to the FDA-approved indications for their already-approved products by submitting “supplemental new drug applications” that include data to demonstrate safety and efficacy for the new indication(s). The FDA can also initiate changes in the list of indications, most frequently based on evidence that raises safety concerns about an existing indication. Most labeling changes for branded products are well publicized but the same may not be true for all drugs listed in the database. As a consequence, the only way to ensure that the list of FDA-approved indications is current for every drug is to review every drug's label. This will be done

monthly, so there will be a lag as long as 1 month in the currency of the indications in the database. The date of completion of the most recent review of indications appears in parentheses after the heading "FDA-Approved Indications" on each individual drug page.

- Manufacturer contact information. All contact information in the database will be verified on a quarterly basis. The date of its most recent verification appears (in parentheses) after each phone number.