

Change in Coverage for Certain Covered Outpatient Drugs (COD)

NYRx, the Medicaid Pharmacy Program, covers medically necessary FDA-approved drugs when used for Medicaid-covered indications. Some unapproved drugs are allowed to remain in the marketplace due to Food and Drug Administration (FDA) exceptions; however, these drugs have not been evaluated for safety and efficacy. NYRx covers certain unapproved drugs, as permitted by federal law, in circumstances such as a drug shortage of an approved drug, or when the Program has determined the drug to be medically necessary, such that without the drug it would cause a significant impact in the health of Medicaid members, and when there is no FDA- approved alternative to treat the medical condition.

The following drugs have not been evaluated for safety and efficacy and are unavailable from the List of Reimbursable Drugs:

- √ Hydroxym (hydrocortisone gel)
- ✓ Lidocort (lidocaine/hydrocortisone acetate cream)
- ✓ Methenamine mandelate tablets
- ✓ Oracit (citric acid, sodium citrate, solution)
- ✓ Salsalate tablets
- ✓ Sulfacetamide Sodium/sulfur cream, foam, suspension
- ✓ Urelle (hyoscyamine sulfate, methenamine, methylene blue, phenyl salicylate, sodium phosphate monobasic tablet)
- ✓ Urogesic Blue (Methenamine, Sodium Phosphate, Methylene Blue, Hyoscyamine Sulfate tablet)

Note: the drugs in the above list have FDA approved safe and effective alternatives for their common uses. Prescribers may consider FDA approved alternatives using the Medicaid Pharmacy List of Reimbursable Drugs found here: https://www.emedny.org/info/formfile.aspx

The Program will continue to monitor unapproved drugs and will make updates as determined.

If a prescriber has determined that one of these unapproved drugs is the only appropriate treatment for a Medicaid member, they may submit a letter of medical necessity and supporting documentation to NYRx@health.ny.gov for a review of available coverage.

If you have questions on the Policy, contact NYRx at: NYRx@health.ny.gov.

Revision: 10/8/2025, changes highlighted