

- (2) Quantity dispensed;
- (3) Price;
- (4) Prescription number (for reference purposes only); and
- (5) Date dispensed; and

4. Inspect records of purchases of covered drugs for which claims have been made for reimbursement.

10:51-2.4 Program restrictions affecting payment of prescribed drugs

(a) The choice of prescribed drugs shall be at the discretion of the prescriber within the limits of applicable laws. However, the prescriber's discretion is limited for certain drugs. Reimbursement may be denied if the requirements of the following rules are not met:

1. Covered and non-covered pharmaceutical services as listed in N.J.A.C. 10:51-2.10 and 2.11, respectively;
2. Quantity of medication (see N.J.A.C. 10:51-2.12);
3. Pharmaceutical services requiring pharmacist intervention as part of the Medicaid prospective drug utilization review (PDUR) program (see N.J.A.C. 10:51-2.23);
4. Dosage and directions (see N.J.A.C. 10:51-2.13);
5. Prescriptions and in-patient medication orders rendered by telephone or technological devices (see N.J.A.C. 10:51-2.14);
6. Changes or additions to the original prescription or in-patient medication order (see N.J.A.C. 10:51-2.15);
7. Prescription refill (see N.J.A.C. 10:51-2.16);
8. Prescription Drug Price and Quality Stabilization Act (N.J.S.A. 24:6E-1 et seq.) (see N.J.A.C. 10:51-2.17);
 - i. Products listed in the current New Jersey Drug Utilization Review Council (DURC) Formulary (hereafter referred to as "the Formulary"), and all subsequent revisions, distributed to all prescribers and pharmacists; and
 - ii. Non-proprietary or generic dispensing (see N.J.A.C. 10:51-2.9);
9. Federal regulations (42 CFR 447.301, 331-333) that set the aggregate upper limits on payment for certain multi-source drugs if Federal Financial Participation (FFP) is to be made available. The limit applies to all "maximum allowable cost" drugs (see N.J.A.C. 10:51-2.5, Basis of payment);
10. Drug Efficacy Study Implementation (DESI): "Less than effective drugs" subject to a Notice of Opportunity for Hearing (NOOH) by the Federal Food and Drug Administration (see N.J.A.C. 10:51-2.18 and listing of DESI drugs in Appendix A); and

11. Drug Manufacturers' Rebate Agreement with the Health Care Financing Administration of the United States Department of Health and Human Services (see N.J.A.C. 10:51-2.18).

Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).

See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).

10:51-2.5 Basis of payment

(a) This section provides a summary of the elements involved in the calculation of the payment of a legend drug. The elements include the following:

1. Program restrictions affecting reimbursement for the dispensing of drugs as listed in N.J.A.C. 10:51-2.4;
2. Price information as supplied from a reference drug file subcontracted for this purpose by the fiscal agent and accepted by the Division as the primary source of pricing information for the New Jersey Medicaid Management Information System (NJMMIS). The drug price or ingredient cost shall not exceed the lower of the average wholesale price as supplied by the reference drug file contractor; the provider's usual and customary charge; or the drug's Maximum Allowable Cost, if applicable (see (b) below);
 - i. The NJMMIS reference drug file is updated periodically by the fiscal agent based upon data supplied by First Data Bank (FDB). The update process provides the fiscal agent with current data to include changes in product description. Providers are made aware of therapeutic indications for various classes of drugs by product literature distributed by drug manufacturers and by various trade publications. Based on market information, providers can determine whether a product's therapeutic classification meet the criteria specified in N.J.A.C. 10:51-2.10 (Covered pharmaceutical services).
3. Federal regulations (42 CFR 447.301, 331-333) that set the aggregate upper limits on payment for certain covered drugs in the pharmaceutical program. The New Jersey Medicaid program refers to these upper limits as the "maximum allowable cost" (see (b) below); and
4. The provider's usual and customary charge for legend drugs (see (c) below), contraceptive diaphragms and legend devices.

(b) Payment for legend drugs, contraceptive diaphragms, and reimbursable legend devices, is based upon the maximum allowable cost. This means the lower of the upper payment limit price list (MAC price) as published by the federal government or the average wholesale price (AWP). See Appendix B for the listing of MAC drugs.

1. Maximum allowable cost is defined as:
 - i. The MAC price for listed multi-source drugs published periodically by the Health Care Financing

Administration (HCFA) of the United States Department of Health and Human Services; or

ii. For legend drugs not included in (b)1i above, the Estimated Acquisition Cost (EAC), which is defined as the average wholesale price (AWP) listed for the package size (billed to the New Jersey Medicaid program), in current national price compendia or other appropriate sources (such as the First Data Bank (FDB) reference drug file contractor), and their supplements, minus regression category or discount.

2. For information about the "regression categories and discounts," see N.J.A.C. 10:51-2.6.

3. If the published MAC price as defined in (b)1i above is higher than the maximum allowable cost which would be paid as defined in (b)1ii above, then (b)1ii above shall apply.

(c) For claims with service dates on or after the July 15, 1996, the maximum cost for each eligible prescription claim not covered by the Maximum Allowable Cost price, as defined in N.J.A.C. 10:51-2.5(b)1i is based on the average wholesale price (AWP) of a drug, as defined in (b)1ii above, less a discount of 10 percent.

Amended by R.1997 d.251, effective June 16, 1997.

See: 28 N.J.R. 2481(a), 28 N.J.R. 3221(a), 29 N.J.R. 2690(a).

In (a), deleted reference to non-legend drugs; in (b)1ii, inserted "For legend drugs not included in (b)1i above," and "minus regression category or discount"; deleted the first sentence of former (b)1ii(1) and recodified the remaining text as (b)2; recodified former (b)2 as (b)3; in (b)3, substituted "maximum allowable cost" for "average wholesale price"; and added (c).

10:51-2.6 Regression categories and discounts

(a) For pharmaceutical services provided prior to July 15, 1996, the maximum cost for each eligible prescription claim not covered by the maximum allowable cost price (see N.J.A.C. 10:51-2.5, Basis of payment) shall be subject to the following fiscal conditions based upon six categories. The category, as determined by the New Jersey Medicaid program, is based on the previous year's total prescription volume for each participating pharmacy. The categories shall be reviewed annually and adjusted as appropriate.

1. Those pharmacy providers who have been in business for less than one calendar year shall have their prescription volume projected for the entire year, to determine the appropriate category.

(b) For pharmaceutical services provided prior to July 15, 1996, the pharmacy provider shall submit, in writing, an annual report on form FD-70 (see Appendix C, Pharmacy Provider Certification Statement) certifying its prescription volume. The Division shall determine a provider's total prescription volume, which includes all prescriptions filled (both new and refills), including nursing facility prescriptions, for private patients, Medicaid, PAAD, and other third party recipients for the previous calendar year. Failure to submit this report annually shall result in the provider being placed in the maximum discount category (category VI) for the year of non-compliance, or until the required report is received.

1. Category I: Pharmacies whose total prescription volume in the preceding calendar year was not more than 14,999 prescriptions.

i. For service dates prior to January 2, 1996, pharmacy providers in this category shall receive reimbursement for Medicaid prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 10:51-2.5—as the maximum. For claims with service dates on or after January 2, 1996, reimbursement shall be based on AWP less two percent as the maximum.

2. Category II: Pharmacies whose total prescription volume in the preceding calendar year was at least 15,000 but not greater than 19,999 prescriptions.

i. For service dates prior to January 2, 1996, pharmacy providers in this category shall receive reimbursement for Medicaid prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 10:51-2.5, less two percent, as the maximum. For claims with service dates on or after January 2, 1996, reimbursement shall be based on AWP less four percent as the maximum.

3. Category III: Pharmacies whose total prescription volume in the preceding calendar year was at least 20,000 but not greater than 29,999 prescriptions.

i. For service dates prior to January 2, 1996, pharmacy providers in this category shall receive reimbursement for Medicaid prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 10:51-2.5, less three percent, as the maximum. For claims with service dates on or after January 2, 1996, reimbursement shall be based on AWP less five percent as the maximum.

4. Category IV: Pharmacies whose total prescription volume in the preceding calendar year was at least 30,000 but not greater than 39,999 prescriptions.

i. For service dates prior to January 2, 1996, pharmacy providers in this category shall receive reimbursement for Medicaid prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 10:51-2.5, less four percent, as the maximum. For claims with service dates on or after January 2, 1996, reimbursement shall be based on AWP less six percent as the maximum.

5. Category V: Pharmacies whose total prescription volume in the preceding calendar year was at least 40,000 but not greater than 49,999 prescriptions.

i. For service dates prior to January 2, 1996, pharmacy providers in this category shall receive reimbursement for Medicaid prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 10:51-2.5, less five percent, as the maximum. For claims with service dates on or after January 2, 1996, reimbursement shall be based on AWP less seven percent as the maximum.