3.1. **AMOUNT, DURATION AND SCOPE OF ASSISTANCE**

Covered outpatient drugs are those produced by any manufacturer, which has entered into and complied with a rebate agreement under Social Security Act § 1927(a), which are prescribed for a medically accepted indication. A covered outpatient drug does not include any drug, biological product or insulin provided as part of or incident to and in the same setting as defined in Social Security Act § 1927(k)(3) for which payment includes drugs, biological products and insulin. Medicaid will not cover Part D drugs for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.

Limitations in Coverage

A. Exclusions and restrictions on certain drugs or classes of drugs:

The Medicaid agency provides coverage for the following excluded or otherwise restricted drugs or classes of drugs, or their medical uses to all Medicaid recipients, including full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit -Part D.

The following marked excluded drugs are covered:

___ a. Agents when used for anorexia, weight loss, weight gain.

___ b. Agents when used to promote fertility.

_X_ c. Selected agents, when used for the symptomatic relief of cough and colds, are covered. These agents can be found on West Virginia Medicaid's approved coverage list, which is updated periodically.

_X_ d. Selected prescription vitamins and mineral products are covered. These agents can be found on West Virginia Medicaid's approved coverage list which is updated periodically. Selective vitamins and mineral products will be covered as listed on the state's website. Legend vitamins A, D, K and niacin. Minerals include calcium, iron, magnesium, and additional mineral requirements for the treatment of End Stage Renal Disease (ESRD). All legend vitamins are covered for recipients in the ESRD Program.

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_X_ e. Nonprescription drugs: Selective non-prescription (over the counter) medications will be covered as listed on the state's website.

___ f. Drugs described in §107(c)(3) of the drug Amendments of 1962 and identical, similar or related drugs (within the meaning of §310.6(b)(1) of Title 21 of the Code of Federal Regulations ("DESI" drugs).

___ g. Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services will be purchased exclusively from the manufacturer or its designee.

B. Drugs covered with limitation (applicable to all covered drug categories)

a. Certain drugs identified by high cost, high risk or high use are subject to limitations through prior authorization as to units or coverage periods.

b. Certain drugs are limited by gender or age according to FDA approved indications. Prior authorization is available on a case-by-case basis for exceptions with medical necessity justification.

3.1. **AMOUNT, DURATION AND SCOPE OF ASSISTANCE**

C. Quantities and Duration

1. Covered outpatient drugs are reimbursed up to 34-day supply per prescription. The number of refills per prescription will be in accordance with state and federal law and regulations.

2. Certain drugs are limited by quantity, number of allowable refills of duration or use.

D. Drug Rebate Agreements

The state is in compliance with §1927 of the Social Security Act. The state will cover drugs of federal rebate participating manufacturers. The state is in compliance with reporting requirements for utilization and restrictions to coverage. Pharmaceutical manufacturers can audit utilization data. The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification.

The state will be negotiating supplemental rebates in addition to the federal rebates provided for in Title XIX. Rebate agreements between the state and a pharmaceutical manufacturer will be separate from the federal rebates.

A rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid program, submitted to CMS on January 1, 2008, and entitled "West Virginia Medicaid Supplemental Drug Rebate Agreement" has been authorized by CMS.

CMS has authorized the state of West Virginia to enter in the Sovereign States Drug Consortium (SSDC) multistate pool. This Supplemental Drug Rebate Agreement was submitted to CMS on September 30, 2008, and has been authorized by CMS effective August 1, 2008. A revised SSDC Supplemental Rebate Agreement was authorized by CMS, effective January 1, 2015, for any renewal and new agreements with pharmaceutical manufacturers for drugs provided to Medicaid recipients.

Supplemental rebates received by the state in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national rebate agreement.

All drugs covered by the program, irrespective of a prior authorization requirement, will comply with the provision of the national drug rebate agreement.

All drugs covered by the program, irrespective of a prior authorization requirement, will comply with the provision of the national drug rebate agreement.

E. Preferred Drug List with Prior Authorization

1. Pursuant to 42 U.S.C§1396r-8 and WV Code §9-5-15, the state is establishing a preferred drug list with prior authorization for drugs not included on the preferred list. Prior authorization will be provided with a 24-hour turn-around from receipt of request and a 72-hour supply of drugs in an emergency circumstance.

2. Prior authorization will be established for certain drug classes, particular drugs, or medically accepted indication for uses and doses.

3. The state will appoint a Pharmaceutical and Therapeutic Committee or utilize the drug utilization review committee in accordance with federal law.