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DOCUMENT HISTORY

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DRAFT - Final Documents to be provided to awarded Contractor

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This document delineates the prescription and non-prescription drug benefit for the Medicaid Managed Care Services¹. The provisions outlined below have been implemented across all Medicaid Managed Care Services.

I. General Statement of Policy

The Medicaid Managed Care Services has a comprehensive pharmacy benefit available to all enrollees. The comprehensive pharmacy benefit includes prescription drugs and non-prescription drugs as defined in this document and in accordance the Contractor's formulary. It also includes: glucometers, test strips, lancet and lancet devices and miscellaneous supplies (including alcohol swabs and calibration fluid).

II. Generic First

The Generic First program is limited to generic drugs, approved by the U.S. Food and Drug Administration (FDA), as designated by National Compendia or other recognized database, e.g. Medispan or First Data Bank, as well as for those therapeutic classes of drugs/ single agents specifically listed in Section II (A) below². When the prescription drug benefit is limited to the generic product or the lowest net cost alternative, requests for coverage of the brand and/or a costlier agent will be reviewed on a case-by-case basis. Brand name drugs and/or more costly agents are available based on Medical Necessity and demonstrated lack of efficacy of generic drugs and/or the lowest net cost alternative.

The Contractor may establish its own *Drug Formulary* to meet the prescription drug needs of the enrollees. *Drug Formulary* means the prescription medications and dosage forms covered. As a component of its *Drug Formulary*, the Contractor may establish prior authorization (PA) requirements for certain drugs.

A. Medicaid Managed Care Services - Allowed Brand Name Therapeutic Classes /Single Agents

Subject to periodic update and revision, the following therapeutic classes of drugs/single agents are allowed in the Medicaid Managed Care Services Prescription Drug Benefit:

¹ This applies to all Lines of Business. It does not apply to individuals with traditional Medicaid (fee for service) coverage.

² Policy exception to this requirement based on Medically Necessity is further described in Section II (F).


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Table 1 Medicaid Managed Care - Allowed Brand Name Therapeutic Classes /Single Agents	
Anti-Parasitics/Antihelmintics	Insulins (ALL)
Abilify Maintena	Insulin Syringes (ALL)
Antivirals (HIV/AIDs only)	Lupron (Gender Dysphoria diagnosis)
Beta-Agonist Inhalers (including combo products)	Invega Sustenna
Aristada	Invega Trinza
CF Agents (ALL)	Makena
Contraceptives (intravaginal only)	Mesalamine Related Products (Apriso®, Asacol, Pentasa, Dipentum, Lialda only)
Cosentyx	Multiple Sclerosis Agents
Dilantin Only	Narcan Nasal Spray
Ella®	Oral Antineoplastic Agents (ALL)
Epi-Pens	Orphan Drugs and Drugs for Rare Diseases
	Oral anticoagulants (Eliquis, BevyxXa, Pradaxa, Savaysa, Xarelto)
Erythropoietin Products	PAH agents (ALL)
Estrogen Replacement (Premarin, Prempro, Premphase, Duavee only)	Pancreatic Enzymes
GCSF Agents (Leukine, Neulasta, Neupogen)	Pulmozyme
Glucometers, lancets, test strips, misc. supplies	Relenza (CDC H1N1 Flu)
Growth Hormones (ALL)	Risperdal Consta
Glucagon	LAMA inhalers (Spiriva®, Tudorza®)
Hemophilia drugs	
Hepatitis C Agents (all routes)	Synagis®
HP Acthar Gel	Tamiflu (CDC – H1N1 Flu)
Immunosuppressant's (Prograf, Cellcept, Rapamune)	(Discontinued product)
Inhaled Corticosteroids (including combo products)	

Within each class defined as brand name drugs that are allowed, the Contractor may maintain its own proprietary preferred drug list (PDL). Those drug products not included on the Contractor's PDL, but not excluded from coverage, may be managed through the standard utilization rules as outlined in each Health Plan's administrative procedures.

B. Exclusions

The following items are not covered when obtained at a pharmacy:

1. Biological products for allergy immunizations
2. Biological products for vaccinations
3. Blood fractions
4. Compound medications that are not made up of at least one *legend drug*
5. Drugs prescribed or dispensed outside of Health Plan dispensing guidelines
6. Drugs that have not been proven effective according to the FDA

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7. Drugs used for cosmetic purposes
8. Experimental drugs (including those placed on notice of opportunity hearing status by the Federal Drug Efficacy Study Implementation (DESI))
9. Medications an enrollee may take or was given while a patient in a hospital, rest home, sanitarium, nursing home, home care program, or other institution that provides prescription drugs as part of its services or which operates its own facility for dispensing prescription drugs
10. Non-medical substances (regardless of the reason prescribed, the intended use, or Medical Necessity)
11. Off-label use of drugs;
12. Support garments and other durable medical equipment;
13. Therapeutic devices and appliances, including hypodermic needles and syringes (except when used to administer insulin or for self-administration of injectable drugs);
14. Medications used for the treatment of erectile dysfunction (ED).

Except for the drugs listed in Table 1 or determined to be medically necessary under Section II (F) below, any brand name drug is defined as a non-covered product.

A Health Plan may establish a policy not to cover prescription drugs and diabetic equipment/supplies when purchased from a *non-network* mail order pharmacy.

A Health Plan may establish a policy not to cover drugs purchased from a mail order pharmacy.

A prescription drug refill will not be covered if the refill is:


- Greater than the refill number authorized by the physician or other authorized provider
- Greater than the twelve (12) refills authorized
- Limited by law
- Refilled more than a year from the date of the original prescription.

C. Replacement Prescription Drug Products

A Health Plan may establish policy and procedures pertaining to coverage for replacement prescription drug products resulting from a lost, stolen, broken, or destroyed prescription order or refill. The policy and procedures shall be subject to the prior approval by the Rhode Island Executive Office of Health and Human Services (EOHHS).

D. Non-Prescription Drugs

Over-the-counter drugs are covered when prescribed by a physician or other authorized provider. This component of the Generic First Pharmacy Benefit includes emergency contraception, nicotine cessation supplies ordered by a Health Plan physician/practitioner, and medically necessary nutritional supplements ordered by a Health Plan physician/practitioner, whether or not covered by the Rhode

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Island Medical Assistance Program. At a minimum, the Health Plan shall cover OTC agents/classes as covered by the EOHHS Fee for Service program.

E. Family Planning Drugs

Family planning drugs and supplies are limited to those in the *RI Medicaid Managed Care Services Contract* for members enrolled under the Extended Family Planning (EFP) Benefit. Family Planning drugs and supplies for all other members are covered as medically necessary in accordance with the Generic First Pharmacy Benefit.


F. Allowing Coverage of Brand Name Drugs on a Case-by-Case Basis/ Medical Necessity Review Criteria

Brand name drugs beyond those included in Table 1 can be covered as an exception, based on patient specific documentation of need by the prescribing practitioner. Coverage by the health plan of brand name drugs in a therapeutic class or single agent not included in Table 1 is permissible on a case-by-case basis, based on Medical Necessity and demonstrated lack of efficacy of a generic drug for an individual patient. The Health Plan shall establish Policies and Procedures for direct practitioner attestation of need.

Criteria to be used for the evaluation of brand name drug coverage due to Medical Necessity and/or demonstrated lack of efficacy of generic drugs are outlined as follows:

1. Patient has experienced an inadequate therapeutic response following a trial, with at least two different, if available and clinically appropriate³, either generic or Formulary agents. Trial requires appropriate dose of generic agent or Formulary agent (up to maximum recommended dose) and minimum duration of therapy.
2. Patient has experienced a documented side effect and/or intolerance to a trial, with at least two different, if available and clinically appropriate³, either generic or Formulary agents. Documentation of side effect and/or intolerance to generic or Formulary agent must be noted in the patient's medical record. Trial requires appropriate dose of generic agent or Formulary agent (up to maximum recommended dose) and minimum duration of therapy.
3. Documentation of a generic trial that the patient cannot be stabilized on a generic agent.
4. Use of all generic and Formulary agent(s) of a brand name drug is contraindicated for a patient's specific condition.

³ Supported by information from the appropriate compendia of current literature (American Hospital Formulary Service Drug Information, National Comprehensive Cancer Network Drugs and Biologics Compendium, Thomson Micromedex DrugDex, Clinical Pharmacology, clinical practice Guidelines, etc.).

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III. Medicaid Managed Care Services Pharmacy Benefit Review Committee

The Executive Office of Health and Human Services has established a Medicaid Managed Care Services Prescription Drug Benefit Review Committee to assist in the components of periodic updates and reviews of the current list of Medicaid Managed Care Services -Allowed Brand Name Therapeutic Classes/Single Agents (Table1) and criteria for the case-by-case allowance of brand name drugs Medical Necessity process.

A. Composition of the Committee

The Committee will be composed of representatives of the Executive Office of Health and Human Services, each of the participating health plans pharmacy representatives, including a physician.

B. Duties of the Committee include the following:

1. Assist in the periodic review and revisions of Table 1.
2. Recommend criteria for the case-by-case exception process.
3. Recommend protocols for communicating recommended revisions to Table 1.

C. Guidelines for Revisions to Table 1

In establishing recommendations for revisions to Table 1, the Committee shall meet at least on an annual basis and will consider various characteristics of the drug and the clinical conditions under which it is prescribed. Review criteria may include, but not be limited to:

1. Availability of suitable within-class generic substitutes or out-of-class alternatives.
2. Drugs with a narrow therapeutic range that are regarded as the standard of care for treating specific conditions.
3. Relative disruptions in care that may be brought on by changing treatment from one drug to another.
4. Relative medical management concerns for drugs that can only be used to treat patients with specific co-morbidities.
5. Relative clinical advantages and disadvantages of drugs within a therapeutic class.
6. Cost differentials between brand and generic alternatives.
7. Drugs that are required under Federal and State regulations.
8. Demonstrated Medical Necessity and lack of efficacy on a case-by-case basis.