

## SECTION XIII

### Prescription Drug Coverage

Please refer to the Schedule of Benefits section of this [Contract; Policy] for Cost-Sharing requirements, day or visit limits, and any Preauthorization or Referral requirements that apply to these benefits.

*{Drafting Note: HMOs and gatekeeper EPO products may not impose preauthorization requirements on the member for in-network coverage.}*

#### **A. Covered Prescription Drugs.**

We Cover Medically Necessary Prescription Drugs that, except as specifically provided otherwise, can be dispensed only pursuant to a prescription and are:

- Required by law to bear the legend “Caution – Federal Law prohibits dispensing without a prescription”;
- FDA approved;
- Ordered by a Provider authorized to prescribe and within the Provider’s scope of practice;
- Prescribed within the approved FDA administration and dosing guidelines; and
- On Our Formulary;] and
- Dispensed by a licensed pharmacy.

*{Drafting Note: Insert the formulary bullet for plans that use a closed formulary to list covered prescription drugs. The bullet may be omitted for plans with an open formulary.}*

Covered Prescription Drugs include, but are not limited to:

- Self-injectable/administered Prescription Drugs.
- Inhalers (with spacers).
- Topical dental preparations.
- Pre-natal vitamins, vitamins with fluoride, and single entity vitamins.
- Osteoporosis drugs [and devices] approved by the FDA, or generic equivalents as approved substitutes, for the treatment of osteoporosis and consistent with the criteria of the federal Medicare program or the National Institutes of Health.  
*{Drafting Note: Osteoporosis devices should be covered as part of the prescription drug benefit; however, if the cost-sharing is more favorable under the durable medical equipment benefit, plans may delete the reference to devices.}*
- Nutritional formulas for the treatment of phenylketonuria, branched-chain ketonuria, galactosemia and homocystinuria.
- Prescription or non-prescription enteral formulas for home use, whether administered orally or via tube feeding, for which a Physician or other licensed Provider has issued a written order. The written order must state that the enteral formula is Medically Necessary and has been proven effective as a disease-specific treatment regimen. Specific diseases and disorders include but are not limited to: inherited diseases of amino acid or organic acid metabolism; Crohn’s

disease; gastroesophageal reflux; gastroesophageal motility such as chronic intestinal pseudo-obstruction; and multiple severe food allergies. Multiple food allergies include, but are not limited to: immunoglobulin E and nonimmunoglobulin E-mediated allergies to multiple food proteins; severe food protein induced enterocolitis syndrome; eosinophilic disorders and impaired absorption of nutrients caused by disorders affecting the absorptive surface, function, length, and motility of the gastrointestinal tract.

- Modified solid food products that are low in protein, contain modified protein, or are amino acid based to treat certain inherited diseases of amino acid and organic acid metabolism and severe protein allergic conditions.
- Prescription Drugs prescribed in conjunction with treatment or services Covered under the infertility treatment benefit in the Outpatient and Professional Services section of this [Contract; Policy].
- Off-label cancer drugs, so long as the Prescription Drug is recognized for the treatment of the specific type of cancer for which it has been prescribed in one (1) of the following reference compendia: the American Hospital Formulary Service-Drug Information; National Comprehensive Cancer Networks Drugs and Biologics Compendium; Thomson Micromedex DrugDex; Elsevier Gold Standard's Clinical Pharmacology; or other authoritative compendia as identified by the Federal Secretary of Health and Human Services or the Centers for Medicare and Medicaid Services; or recommended by review article or editorial comment in a major peer reviewed professional journal.
- Orally administered anticancer medication used to kill or slow the growth of cancerous cells.
- Smoking cessation drugs including over-the-counter drugs for which there is a written order and Prescription Drugs prescribed by a Provider.
- Preventive Prescription Drugs, including over-the-counter drugs for which there is a written order, provided in accordance with the comprehensive guidelines supported by the Health Resources and Services Administration ("HRSA") or that have an "A" or "B" rating from the United States Preventive Services Task Force ("USPSTF").
- Prescription Drugs for the treatment of mental health and substance use disorders, including drugs for detoxification, maintenance and overdose reversal.
- Contraceptive drugs, devices and other products, including over-the-counter contraceptive drugs, devices and other products, approved by the FDA and as prescribed or otherwise authorized under State or Federal law. "Over-the-counter contraceptive products" means those products provided for in comprehensive guidelines supported by HRSA. Coverage also includes emergency contraception when provided pursuant to a prescription or order or when lawfully provided over-the-counter. You may request coverage for an alternative version of a contraceptive drug, device and other product if the Covered contraceptive drug, device and other product is not available or is deemed medically inadvisable, as determined by Your attending Health Care Provider.]

You may request a copy of Our Formulary. Our Formulary is also available on Our website [at XXX]. You may inquire if a specific drug is Covered under this [Contract; Policy] by contacting Us at [XXX; the number on Your ID card].

## **B. Refills.**

We Cover Refills of Prescription Drugs only when dispensed at a retail [or mail order] [or Designated] pharmacy as ordered by an authorized Provider [and only after  $\frac{3}{4}$  of the original Prescription Drug has been used]. Benefits for Refills will not be provided beyond one (1) year from the original prescription date. For prescription eye drop medication, We allow for the limited refilling of the prescription prior to the last day of the approved dosage period without regard to any coverage restrictions on early Refill of renewals. To the extent practicable, the quantity of eye drops in the early Refill will be limited to the amount remaining on the dosage that was initially dispensed. Your Cost-Sharing for the limited Refill is the amount that applies to each prescription or Refill as set forth in the Schedule of Benefits section of this [Contract; Policy].

*{Drafting Note: The bracketed language above is optional.}*

## **C. Benefit and Payment Information.**

- 1. Cost-Sharing Expenses.** You are responsible for paying the costs outlined in the Schedule of Benefits section of this [Contract; Policy] when Covered Prescription Drugs are obtained from a retail, [or mail order], [or Designated] pharmacy.

*{Drafting Note: Include the bracketed language if mail order is available. Mail order may be offered in the Essential Plan but is not required}*

You have a three (3) tier plan design, which means that Your out-of-pocket expenses will generally be lowest for Prescription Drugs on tier 1 and highest for Prescription Drugs on tier 3. Your out-of-pocket expense for Prescription Drugs on tier 2 will generally be more than for tier 1 but less than tier 3.

You are responsible for paying the full cost (the amount the pharmacy charges You) for any non-Covered Prescription Drug, and Our contracted rates (Our Prescription Drug Cost) will not be available to You.

- 2. Participating Pharmacies.** For Prescription Drugs purchased at a retail [or mail order] [or designated] Participating Pharmacy, You are responsible for paying the lower of:
  - The applicable Cost-Sharing;
  - The Prescription Drug Cost for that Prescription Drug; or  
(Your Cost-Sharing will never exceed the Usual and Customary Charge of the Prescription Drug.)

[In the event that Our Participating Pharmacies are unable to provide the Covered Prescription Drug, and cannot order the Prescription Drug within a reasonable time, You may, with Our prior [written] approval, go to a Non-Participating Pharmacy that is able to provide the Prescription Drug. We will pay

You the Prescription Drug Cost for such approved Prescription Drug less Your required Cost-Sharing [upon receipt of a complete Prescription Drug claim form]. Contact Us at [XXX; the number on Your ID card] [or visit Our website [at XXX]] to request approval.]

*{Drafting Note: The bracketed paragraph above is required for HMO and EPO coverage and optional for PPO coverage. Bracketed language within the paragraph (for example “written”) is optional.}*

3. **Non-Participating Pharmacies.** We will not pay for any Prescription Drugs that You purchase at a Non-Participating retail [or mail order] Pharmacy other than as described above.
4. **[Designated Pharmacies.** If You require certain Prescription Drugs including, but not limited to specialty Prescription Drugs, We may direct You to a Designated Pharmacy with whom We have an arrangement to provide those Prescription Drugs.

Generally, specialty Prescription Drugs are Prescription Drugs that are approved to treat limited patient populations or conditions; are normally injected, infused or require close monitoring by a Provider; or have limited availability, special dispensing and delivery requirements and/or require additional patient supports.

If You are directed to a Designated Pharmacy and You choose not to obtain Your Prescription Drug from a Designated Pharmacy, You will not have coverage for that Prescription Drug.

Following are the therapeutic classes of Prescription Drugs or conditions that are included in this program:

- [Age related macular edema;
- Anemia, neutropenia, thrombocytopenia;
- Contraceptives;
- Cardiovascular
- Crohn’s disease;
- Cystic fibrosis;
- Cytomegalovirus;
- Endocrine disorders/neurologic disorders such as infantile spasms;
- Enzyme deficiencies/liposomal storage disorders;
- Gaucher’s disease;
- Growth hormone;
- Hemophilia;
- Hepatitis B, hepatitis C;
- Hereditary angioedema;
- HIV/AIDS;
- Immune deficiency;

- Immune modulator;
- Infertility;
- Iron overload;
- Iron toxicity;
- Multiple sclerosis;
- Oncology;
- Osteoarthritis;
- Osteoporosis;
- Parkinson's disease;
- Pulmonary arterial hypertension;
- Respiratory condition;
- Rheumatologic and related conditions (rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, juvenile rheumatoid arthritis, psoriasis)
- Transplant;
- RSV prevention].]

*{Drafting Note: Include if the plan uses Designated Pharmacies. Plans may add to or subtract from the list of drugs specified above.}*

**[5.] [Designated Retail Pharmacy for Maintenance Drugs.** You may also fill Your Prescription Order for Maintenance Drugs for up to a 90-day supply at a Designated retail Pharmacy [after an initial 30-day supply] [, with the exception of contraceptive drugs, devices, or products which are available for a 12-month supply]. You are responsible for paying the lower of:

- The applicable Cost-Sharing; or
  - The Prescription Drug Cost for that Prescription Drug.
- (Your Cost-Sharing will never exceed the Usual and Customary Charge of the Prescription Drug.)

*{Drafting Note: The bracketed language regarding the initial 30-day supply is optional. If used, the language regarding contraceptives must also be inserted.}*

To maximize Your benefit, ask Your Provider to write Your Prescription Order or Refill for a 90-day supply, with Refills when appropriate (not a 30-day supply with three (3) Refills).

Following are the therapeutic classes of Prescription Drugs or conditions that are included in this program:

- [Asthma;
- Blood pressure;
- Contraceptives;
- Diabetes;
- High cholesterol].

You or Your Provider may obtain a copy of the list of Prescription Drugs available through a Designated retail Pharmacy by visiting Our website [at XXX] or by calling [XXX; the number on Your ID card]. The Maintenance Drug list is updated

periodically. Visit Our website [at XXX] or call [XXX; the number on Your ID card] to find out if a particular Prescription Drug is on the maintenance list.]

*{Drafting Note: Include if the plan uses designated retail pharmacies for maintenance drugs. Plans may add to or subtract from the list of drugs or conditions specified above.}*

**[6.] [Mail Order.** Certain Prescription Drugs may be ordered through Our mail order pharmacy [after an initial 30-day supply [, with the exception of contraceptive drugs, devices, or products which are available for -a 12-month supply]]. [We will only Cover drugs that have a restricted distribution by the FDA or require special handling, provider coordination or patient supports through a mail order pharmacy. Other drugs may also be purchased at a mail order pharmacy.] You are responsible for paying the lower of:

- The applicable Cost-Sharing; or
  - The Prescription Drug Cost for that Prescription Drug.
- (Your Cost-Sharing will never exceed the Usual and Customary Charge of the Prescription Drug.)

*{Drafting Note: The bracketed language regarding the initial 30-day supply is optional. If used, the language regarding contraceptives must also be inserted..The bracketed sentences limiting coverage of restricted drugs to mail order pharmacies is optional.}*

To maximize Your benefit, ask Your Provider to write Your Prescription Order or Refill for a 90-day supply, with Refills when appropriate (not a 30-day supply with three Refills). You [will; may] be charged the mail order Cost-Sharing for any Prescription Orders or Refills sent to the mail order supplier regardless of the number of days supply written on the Prescription Order or Refill.

Prescription Drugs purchased through mail order will be delivered directly to Your home or office.

[For Prescription Drugs that have a restricted distribution by the FDA or require special handling, provider coordination or patient supports, You may obtain Your first [two (2)] Prescription Order[s] at a retail Participating Pharmacy. After Your first [two (2)] Prescription Order[s], You must obtain these Prescription Drugs from Our mail order pharmacy [or You must opt out of obtaining Your Prescription Drugs from Our mail order pharmacy]. [You may opt out by visiting Our website [at XXX] or by calling [XXX; the number on Your ID card].] [You must opt out [on an annual basis] [for each different Prescription Drug].]

*{Drafting Note: The bracketed language regarding mail order drugs is optional.}*

We will provide benefits that apply to drugs dispensed by a mail order pharmacy to drugs that are purchased from a retail pharmacy when that retail pharmacy has a participation agreement with [Us] [and; or] [Our vendor] in which it agrees

to be bound by the same terms and conditions as a participating mail order pharmacy.

You or Your Provider may obtain a copy of the list of Prescription Drugs available through mail order by visiting Our website [at XXX] or by calling [XXX; the number on Your ID card].

*{Drafting Note: Mail order drug coverage is optional. If mail order drug coverage is provided, the above language must be used.}*

- [7.] **Tier Status.** The tier status of a Prescription Drug may change periodically, but no more than four (4) times per [calendar year; Plan Year], or when a Brand-Name Drug becomes available as a Generic Drug as described below, based on Our tiering decisions. These changes may occur without prior notice to You. However, if You have a prescription for a drug that is being moved to a higher tier or is being removed from Our Formulary We will notify You at least 30 days before the change is effective. When such changes occur, Your Cost-Sharing may change. You may also request a Formulary exception for a Prescription Drug that is no longer on the Formulary as outlined below and in the External Appeal section of this [Certificate; Contract; Policy]. You may access the most up to date tier status on Our website [at XXX] or by calling [XXX; the number on Your ID card].
- [8.] **When a Brand-Name Drug Becomes Available as a Generic Drug.** When a Brand-Name Drug becomes available as a Generic Drug, the tier placement of the Brand-Name Prescription Drug may change. If this happens, [You will pay the Cost-Sharing applicable to the tier to which the Prescription Drug is assigned] [or] [the Brand-Name Drug will be removed from the Formulary and You no longer have benefits for that particular Brand-Name Drug]. Please note, if You are taking a Brand-Name Drug that is being [excluded] [or] [placed on a higher tier] due to a Generic Drug becoming available, You will receive 30 days' advance written notice of the change before it is effective. You may request a Formulary exception for a Prescription Drug that is no longer on the Formulary as outlined below and in the External Appeal section of this [Contract; Policy].  
*{Drafting Note: Insert one or both of the bracketed provisions above as applicable. Insert the last bracketed sentence if brand-name drugs will be removed from the formulary.}*
- [9.] **Formulary Exception Process.** If a Prescription Drug is not on Our Formulary, You, Your designee or Your prescribing Health Care Professional may request a Formulary exception for a clinically-appropriate Prescription Drug in writing, electronically or telephonically. [The request should include a statement from Your prescribing Health Care Professional that all Formulary drugs will be or have been ineffective, would not be as effective as the non-Formulary drug, or would have adverse effects.] If coverage is denied under Our standard or expedited Formulary exception process, You are entitled to an external appeal as

outlined in the External Appeal section of this [Contract; Policy]. Visit Our website [at XXX] or call [XXX; the number on Your ID card] to find out more about this process.

*{Drafting Note: The bracketed sentence is optional.}*

**Standard Review of a Formulary Exception.** We will make a decision and notify You or Your designee and the prescribing Health Care Professional by telephone [and in writing] no later than 72 hours after Our receipt of Your request. [We will notify You in writing within three (3) business days of receipt of Your request.] If We approve the request, We will Cover the Prescription Drug while You are taking the Prescription Drug, including any refills.

*{Drafting Note: Plans should insert one of the two bracketed options regarding written notification.}*

**Expedited Review of a Formulary Exception.** If You are suffering from a health condition that may seriously jeopardize Your health, life or ability to regain maximum function or if You are undergoing a current course of treatment using a non-formulary Prescription Drug, You may request an expedited review of a Formulary exception. [The request should include a statement from Your prescribing Health Care Professional that harm could reasonably come to You if the requested drug is not provided within the timeframes for Our standard Formulary exception process.] We will make a decision and notify You or Your designee and the prescribing Health Care Professional by telephone [and in writing] no later than 24 hours after Our receipt of Your request. [We will notify You in writing within three (3) business days of receipt of Your request.] If We approve the request, We will Cover the Prescription Drug while You suffer from the health condition that may seriously jeopardize Your health, life or ability to regain maximum function or for the duration of Your current course of treatment using the non-Formulary Prescription Drug.

*{Drafting Note: The bracketed sentence is optional. Also note, plans must make a decision within 24 hours even if a statement from the prescribing health care professional is not included with the request. Plans should insert one of the two bracketed options regarding written notification }*

**[10.] Supply Limits.** [Except for contraceptive drugs, devices or products,] We will pay for no more than a [30; 90]-day supply of a Prescription Drug purchased at a retail pharmacy [or Designated Pharmacy]. You are responsible for [one (1) Cost-Sharing amount; up to three (3) Cost-Sharing amounts] for up to a [30; 90]-day supply. [However, for maintenance drugs We will pay for up to a 90-day supply of a drug purchased at a retail pharmacy. You are responsible for [one (1) Cost-Sharing amount; up to three (3) Cost-Sharing amounts; one (1) Cost-Sharing amount for Prescription Drugs on tier 1 and three (3) Cost-Sharing amounts for Prescription Drugs on tier 2 and tier 3] for a 90-day supply at a retail pharmacy.]



*{Drafting Note: Include the bracketed language if the Plan covers a 90-day supply of maintenance drugs. Plans may insert one of the cost-sharing options from the brackets above.}*

You may have the entire supply (of up to 12 months) of a prescribed contraceptive drug, device, or product dispensed at the same time. Contraceptive drugs, devices, or products are not subject to Cost-Sharing [when provided by a Participating Pharmacy].

[Benefits will be provided for Prescription Drugs dispensed by a mail order pharmacy in a quantity of up to a 90-day supply. You are responsible for one (1) Cost-Sharing amount for a 30-day supply up to a maximum of two (2); two and a half 2.5 Cost-Sharing amount[s] for a 90-day supply.]

*{Drafting Note: Include the bracketed language if mail order is available.}*

*{Drafting Note: The bracketed language below is optional.}*

[Specialty Prescription Drugs may be limited to a 30-day supply when obtained at a [retail] [or] [mail order] pharmacy. You may access Our website [at XXX] or by calling [XXX; the number on Your ID card] for more information on supply limits for specialty Prescription Drugs.]

[Some Prescription Drugs may be subject to quantity limits based on criteria that We have developed, subject to Our periodic review and modification. The limit may restrict the amount dispensed per Prescription Order or Refill and/or the amount dispensed per month's supply. You can determine whether a Prescription Drug has been assigned a maximum quantity level for dispensing by accessing Our website [at XXX] or by calling [XXX; the number on Your ID card]. If We deny a request to Cover an amount that exceeds Our quantity level, You are entitled to an Appeal pursuant to the Utilization Review and External Appeal sections of this [Contract; Policy].]

*{Drafting Note: The language above is optional.}*

**[11.] [Initial Limited Supply of Prescription Opioid Drugs.** If You receive an initial limited prescription for a seven (7) day supply or less of any schedule II, III, or IV opioid prescribed for Acute pain, and You have a Copayment, Your Copayment will be [the same Copayment that would apply to a 30-day supply of the Prescription Drug. If You receive an additional supply of the Prescription Drug within the same 30-day period in which You received the seven (7) day supply, You will not be responsible for an additional Copayment for the remaining 30-day supply of that Prescription Drug.] [prorated. If You receive an additional supply of the Prescription Drug within the 30-day period in which You received the seven (7) day supply, Your Copayment for the remainder of the 30-day supply will also be prorated. In no event will the prorated Copayment(s) total more than Your Copayment for a 30-day supply.]]

*{Drafting Note: Plans should insert one of the bracketed provisions describing the copayments charged for the limited supply.}*

**[12.]Cost-Sharing for Orally-Administered Anti-Cancer Drugs.** Your Cost-Sharing for orally-administered anti-cancer drugs is at least as favorable to You the Cost-Sharing amount, if any, that applies to intravenous or injected anticancer medications Covered under the Outpatient and Professional Services section of this [Contract; Policy].

**[13.][Half Tablet Program.** Certain Prescription Drugs may be designated as eligible for Our voluntary half tablet program. This program provides the opportunity to reduce Your Prescription Drug out-of-pocket expenses by up to 50% by using higher strength tablets and splitting them in half. If You are taking an eligible Prescription Drug, and You would like to participate in this program, please call Your Physician to see if the half tablet program is appropriate for Your condition. If Your Physician agrees, he or she must write a new prescription for Your medication to enable Your participation.

You can determine whether a Prescription Drug is eligible for the voluntary half tablet program by accessing Our website [at XXX] or by calling [XXX; the number on Your ID card].

*{Drafting Note: Insert if the plan has a half tablet program.}*

**[14.] [Split Fill Dispensing Program.** The split fill dispensing program is designed to prevent wasted Prescription Drugs if Your Prescription Drug or dose changes [or if We contact You and You confirm that You have leftover Prescription Drugs from a previous fill]. The Prescription Drugs that are included under this program have been identified as requiring more frequent follow up to monitor response to treatment and reactions. You will initially get [up to] a 15-day supply [(or appropriate amount of medication needed for an average infertility treatment cycle)] of Your Prescription Order for certain drugs filled at a [Designated; retail; mail order] [P;p]harmacy instead of the full Prescription Order. You initially pay [half the 30-day Cost-Sharing; a lesser Cost-Sharing based on what is dispensed; no Cost-Sharing for the initial fill, and the second fill will have a full 30-day Cost-Sharing]. The therapeutic classes of Prescription Drugs that are included in this program are: [Antivirals/Anti-infectives, Infertility, Iron Toxicity, Mental/Neurologic Disorders, Multiple Sclerosis, and Oncology]. [With the exception of Infertility drugs,] [T;t]his program applies for the first 60 days when You start a new Prescription Drug. [For Infertility drugs, the program applies to Your infertility treatment cycle.] This program will not apply upon You or Your Provider's request. You or Your Provider can opt out by visiting Our website [at XXX] or by calling [XXX; the number on Your ID card].

*{Drafting Note: Insert if the plan has a split fill program. The language in brackets for infertility drugs is optional. Plans may add to or subtract from the list of drugs or conditions specified above.}*

#### **D. [Medical Management.**

This [Contract; Policy] includes certain features to determine when Prescription Drugs should be Covered, which are described below. As part of these features, Your prescribing Provider may be asked to give more details before We can decide if the Prescription Drug is Medically Necessary.

*{Drafting Note: The preauthorization paragraphs below are optional. If the preauthorization language is included, use one of the bracketed provisions in the second sentence of the first paragraph that explains how preauthorization works. Please note that the obligation to request preauthorization for prescription drugs is on the provider. In addition, include the first sentence in the second paragraph that explains how the member can determine which drugs require preauthorization.}*

1. **[Preauthorization.** Preauthorization may be needed for certain Prescription Drugs to make sure proper use and guidelines for Prescription Drug coverage are followed. When appropriate, [We will contact Your Provider to determine if Preauthorization should be given] [ask Your Provider to complete a Preauthorization form] [Your Provider will be responsible for obtaining Preauthorization for the Prescription Drug]. [Should You choose to purchase the Prescription Drug without obtaining Preauthorization, You must pay for the cost of the entire Prescription Drug and submit a claim to Us for reimbursement.] Preauthorization is not required for Covered medications to treat substance use disorder, including opioid overdose reversal medications prescribed or dispensed to You.

For a list of Prescription Drugs that need Preauthorization, please visit Our website [at XXX] or call [XXX; the number on Your ID card]. The list will be reviewed and updated from time to time. We also reserve the right to require Preauthorization for any new Prescription Drug on the market or for any currently available Prescription Drug which undergoes a change in prescribing protocols and/or indications regardless of the therapeutic classification, including if a Prescription Drug or related item on the list is not Covered under Your [Contract; Policy]. Your Provider may check with Us to find out which Prescription Drugs are Covered.]

*{Drafting Note: The step therapy paragraph below is optional.}*

- [2.] **[Step Therapy.** Step therapy is a process in which You may need to use one [or more] type[s] of Prescription Drug[s] before We will Cover another as Medically Necessary. A "step therapy protocol" means Our policy, protocol or program that establishes the sequence in which We approve Prescription Drugs for Your medical condition. When establishing a step therapy protocol, We will use recognized evidence-based and peer reviewed clinical review criteria that also takes into account the needs of atypical patient populations and diagnoses. We check certain Prescription Drugs to make sure that proper prescribing guidelines are followed. These guidelines help You get high quality and cost-effective Prescription Drugs. The Prescription Drugs that require Preauthorization under the step therapy program are also included on the Preauthorization drug list. If a step therapy protocol is applicable to Your request for coverage of a Prescription

Drug, You, Your designee, or Your Health Care Professional can request a step therapy override determination as outlined in the Utilization Review section of this [Contract; Policy].]

*{Drafting Note: The therapeutic substitution paragraph below is optional.}*

**[3.] [Therapeutic Substitution.** Therapeutic substitution is an optional program that tells You and Your Providers about alternatives to certain prescribed drugs. We may contact You and Your Provider to make You aware of these choices. Only You and Your Provider can determine if the therapeutic substitute is right for You. We have a therapeutic drug substitutes list, which We review and update from time to time. For questions or issues about therapeutic drug substitutes, visit Our website [at XXX] or call [XXX; the number on Your ID card].]

**[E.] [Limitations/Terms of Coverage.**

*{Drafting Note: The following limitations are permissible. A plan does not need to include all of the limitations. However, if a limitation is included, the language below must be used.}*

1. We reserve the right to limit quantities, day supply, early Refill access and/or duration of therapy for certain medications based on Medical Necessity including acceptable medical standards and/or FDA recommended guidelines.
2. If We determine that You may be using a Prescription Drug in a harmful or abusive manner, or with harmful frequency, Your selection of Participating Pharmacies [and prescribing Providers] may be limited. If this happens, We may require You to select a single Participating Pharmacy [and a single Provider] that will provide and coordinate all future pharmacy services. Benefits will be paid only if [Benefits will be paid only if Your Prescription Orders or Refills are written by the selected Provider or a Provider authorized by Your selected Provider.]. If You do not make a selection within 31 days of the date We notify You, We will select a single Participating Pharmacy [and/or prescribing Provider] for You.
3. Compounded Prescription Drugs will be Covered only when [they contain at least one (1) ingredient that; the primary ingredient] is a Covered legend Prescription Drug, [they are not essentially the same as a Prescription Drug from a manufacturer] and are obtained from a pharmacy that is approved for compounding. [All compounded Prescription Drugs [over \$250] require [Your Provider to obtain] Preauthorization.] [Compounded Prescription Drugs are on tier [2;3].]  
*{Drafting Note: HMOs and EPOs with a gatekeeper using the bracketed preauthorization language must use “Your Provider”. Plans may require preauthorization for all compounded drugs or only those drugs over a set dollar limit.}*
4. Various specific and/or generalized “use management” protocols will be used from time to time in order to ensure appropriate utilization of medications. Such protocols will be consistent with standard medical/drug treatment guidelines. The

primary goal of the protocols is to provide Our members with a quality-focused Prescription Drug benefit. In the event a use management protocol is implemented, and You are taking the drug(s) affected by the protocol, You will be notified in advance.

5. Injectable drugs (other than self-administered injectable drugs) and diabetic insulin, oral hypoglycemics, and diabetic supplies and equipment are not Covered under this section but are Covered under other sections of this [Contract; Policy].
6. We do not Cover charges for the administration or injection of any Prescription Drug. Prescription Drugs given or administered in a Physician's office are Covered under the Outpatient and Professional Services section of this [Contract; Policy].
7. We do not Cover drugs that do not by law require a prescription, except for smoking cessation drugs, over-the-counter preventive drugs or devices provided in accordance with the comprehensive guidelines supported by HRSA or with an "A" or "B" rating from USPSTF, or as otherwise provided in this [Contract; Policy]. We do not Cover Prescription Drugs that have over-the-counter non-prescription equivalents, except if specifically designated as Covered in the drug Formulary, or as otherwise stated in this [Contract; Policy]. Non-prescription equivalents are drugs available without a prescription that have the same name/chemical entity as their prescription counterparts. [We do not Cover repackaged products such as therapeutic kits or convenience packs that contain a Covered Prescription Drug unless the Prescription Drug is only available as part of a therapeutic kit or convenience pack. Therapeutic kits or convenience packs contain one or more Prescription Drug(s) and may be packaged with over-the-counter items, such as gloves, finger cots, hygienic wipes or topical emollients.]  
*{Drafting Note: The bracketed language is optional.}*
8. We do not Cover Prescription Drugs to replace those that may have been lost or stolen.
9. We do not Cover Prescription Drugs dispensed to You while in a Hospital, nursing home, other institution, Facility, or if You are a home care patient, except in those cases where the basis of payment by or on behalf of You to the Hospital, nursing home, Home Health Agency or home care services agency, or other institution, does not include services for drugs.
10. We reserve the right to deny benefits as not Medically Necessary or experimental or investigational for any drug prescribed or dispensed in a manner contrary to standard medical practice. If coverage is denied, You are entitled to an Appeal as described in the Utilization Review and External Appeal sections of this [Contract; Policy].

11. A pharmacy need not dispense a Prescription Order that, in the pharmacist's professional judgment, should not be filled.]

**[F.] General Conditions.**

1. You must show Your ID card to a retail pharmacy at the time You obtain Your Prescription Drug or You must provide the pharmacy with identifying information that can be verified by Us during regular business hours. [You must include Your identification number on the forms provided by the mail order pharmacy from which You make a purchase.]

*{Drafting Note: Insert the bracketed language above as applicable.}*

- [2. Drug Utilization, Cost Management and Rebates.** We conduct various utilization management activities designed to ensure appropriate Prescription Drug usage, to avoid inappropriate usage, and to encourage the use of cost-effective drugs. Through these efforts, You benefit by obtaining appropriate Prescription Drugs in a cost-effective manner. The cost savings resulting from these activities are reflected in the premiums for Your coverage. We may also, from time to time, enter into agreements that result in Us receiving rebates or other funds ("rebates") directly or indirectly from Prescription Drug manufacturers, Prescription Drug distributors or others. Any rebates are based upon utilization of Prescription Drugs across all of Our business and not solely on any one member's utilization of Prescription Drugs. Any rebates received by Us may or may not be applied, in whole or part, to reduce premiums either through an adjustment to claims costs or as an adjustment to the administrative expenses component of Our Prescription Drug premiums. [Any such rebates may be retained by Us, in whole or part, in order to fund such activities as new utilization management activities, community benefit activities and increasing reserves for the protection of members.] [Rebates [will not; may] change or reduce the amount of any Copayment or Coinsurance applicable under Our Prescription Drug coverage.] [If a Prescription Drug is eligible for a rebate, most of the rebate will be used to reduce the Allowed Amount for the Prescription Drug. Your Deductible or Coinsurance is calculated using that reduced Allowed Amount. The remaining value of that rebate will be used to reduce costs for all Members enrolled in coverage. Not all Prescription Drugs are eligible for a rebate, and rebates can be discontinued or applied at any time based on the terms of the rebate agreements. Because the exact value of the rebate will not be known at the time You purchase the Prescription Drug, the amount of the rebate applied to Your claim will be based on an estimate. Payment on Your claim and Your Cost-Sharing will not be adjusted if the later-determined rebate value is higher or lower than Our estimate.]

*{Drafting Note: The paragraph above is optional.}*

**[G.] Definitions.**

Terms used in this section are defined as follows. (Other defined terms can be found in the Definitions section of this [Contract; Policy]).

1. **Brand-Name Drug:** A Prescription Drug that: 1) is manufactured and marketed under a trademark or name by a specific drug manufacturer; or 2) We identify as a Brand-Name Prescription Drug, based on available data resources. All Prescription Drugs identified as “brand name” by the manufacturer, pharmacy, or Your Physician may not be classified as a Brand-Name Drug by Us.
2. **Designated Pharmacy:** A pharmacy that has entered into an agreement with Us or with an organization contracting on Our behalf, to provide specific Prescription Drugs, including but not limited to, specialty Prescription Drugs. The fact that a pharmacy is a Participating Pharmacy does not mean that it is a Designated Pharmacy.
3. **Formulary:** The list that identifies those Prescription Drugs for which coverage may be available under this [Contract; Policy]. This list is subject to Our periodic review and modification (no more than four (4) times per [calendar year; Plan Year] or when a Brand-Name Drug becomes available as a Generic Drug). To determine which tier a particular Prescription Drug has been assigned, visit Our website [at XXX] or call [XXX; the number on Your ID card].
4. **Generic Drug:** A Prescription Drug that: 1) is chemically equivalent to a Brand-Name Drug; or 2) We identify as a Generic Prescription Drug based on available data resources. All Prescription Drugs identified as “generic” by the manufacturer, pharmacy or Your Physician may not be classified as a Generic Drug by Us.
5. **[Maintenance Drug:** A Prescription Drug used to treat a condition that is considered chronic or long-term and which usually requires daily use of Prescription Drugs.]  
*{Drafting Note: Insert the definition of maintenance drug as applicable.}*
6. **Non-Participating Pharmacy:** A pharmacy that has not entered into an agreement with Us to provide Prescription Drugs to Subscribers. [We will not make any payment for prescriptions or Refills filled at a Non-Participating Pharmacy other than as described above.]  
*{Drafting Note: Insert the bracketed language above as applicable.}*
7. **Participating Pharmacy:** A pharmacy that has:
  - Entered into an agreement with Us or Our designee to provide Prescription Drugs to members;
  - Agreed to accept specified reimbursement rates for dispensing Prescription Drugs; and
  - Been designated by Us as a Participating Pharmacy.[A Participating Pharmacy can be either a retail or mail-order pharmacy.]  
*{Drafting note: Include the bracketed sentence above if mail order is available.}*

- 8. Prescription Drug:** A medication, product or device that has been approved by the FDA and that can, under federal or state law, be dispensed only pursuant to a Prescription Order or Refill [and is on Our Formulary]. A Prescription Drug includes a medication that, due to its characteristics, is appropriate for self administration or administration by a non-skilled caregiver.  
*{Drafting Note: The bracketed language above is optional.}*
- 9. Prescription Drug Cost:** The amount, including a dispensing fee and any sales tax, [We have agreed to pay Our Participating Pharmacies; as contracted between Us and Our pharmacy benefit manager] for a Covered Prescription Drug dispensed at a Participating Pharmacy. If Your [Certificate; Contract; Policy] includes coverage at Non-Participating Pharmacies, the Prescription Drug Cost for a Prescription Drug dispensed at a Non-Participating Pharmacy is calculated using the Prescription Drug Cost that applies for that particular Prescription Drug at most Participating Pharmacies.  
*{Drafting Note: Insert the appropriate language from the brackets depending whether the plan contracts directly with participating pharmacies or with a pharmacy benefit manager.}*
- 10. Prescription Order or Refill:** The directive to dispense a Prescription Drug issued by a duly licensed Health Care Professional who is acting within the scope of his or her practice.
- 11. Usual and Customary Charge:** The usual fee that a pharmacy charges individuals for a Prescription Drug without reference to reimbursement to the pharmacy by third parties as required by New York Education Law Section 6826-a.