Section V: The Empire Plan Prescription Drug Program Certificate of Insurance

The Empire Plan Prescription Drug Program Certificate does not apply to Medicare-primary Empire Plan enrollees and dependents enrolled in the Empire Plan Medicare Rx Prescription Drug Plan (PDP). For additional information about your Empire Plan Medicare Rx benefits, see your *Evidence of Coverage* and *Empire Plan Medicare Rx (PDP) Plus Certificate*.

CVS/caremark administers the Empire Plan Prescription Drug Program (the "Program"). CVS/caremark utilizes the administrative and mail distribution services of CVS/caremark Mail Service Pharmacy.

Meaning of Terms Used

The following terms used in this *Certificate* with either upper or lower case initial letters shall have the following meanings.

A. **Ancillary Charge** means the amount in addition to the applicable copayment an enrollee will pay when purchasing a brand-name drug if an A-rated or authorized generic equivalent is available in the market. The amount represents the difference to the Program between the discounted ingredient cost of the dispensed brand-name drug and the discounted ingredient cost of the available generic equivalent if it had been dispensed, not to exceed the actual cost of the drug. The ancillary charge does not apply if an appeal of the mandatory generic substitution requirement is approved by the Plan; however, the enrollee must pay the applicable non-preferred brand copayment.

B. **Appeal** means a request for review of your claim in the event a claim has been denied as not medically necessary or as a result of investigational or experimental use of a covered prescription drug in whole or in part.

C. **Brand-Name Drug** means a prescription drug sold under a trade name other than its chemical name that is manufactured and marketed by a single manufacturer (or single group of manufacturers pursuant to agreement among manufacturers) where the manufacturer holds or held a patent protecting the active ingredient from generic competition.

D. **Compound Drug(s)/Medication(s)** or **Compounded Drug(s)/Medication(s)** means a drug with two or more ingredients (solid, semi-solid or liquid), where the primary active ingredient is an FDA-approved covered drug with a valid National Drug Code (NDC) requiring a prescription for dispensing, combined together in a method specified in a prescription issued by a medical professional. The end result of this combination must be a prescription drug for a specific patient that is not otherwise commercially available in that form or dose/strength from a single manufacturer. The prescription must identify the multiple ingredients in the compound, including active ingredient(s), diluent(s), ratios or amounts of product, therapeutic use and directions for use. The act of compounding must be performed or supervised by a licensed pharmacist. Any commercially available product with a unique assigned NDC requiring reconstitution or mixing according to the FDA-approved package insert prior to dispensing will not be considered a compound prescription by this Program.

E. **Controlled Drug** means a drug designated by Federal Law or New York State law as a Class I, II, III, IV or V substance. A controlled drug includes, but is not limited to, some tranquilizers, stimulants and pain medications.

F. **Designated Specialty Pharmacy** means a pharmacy that has entered into an agreement with the Prescription Drug Program administrator to provide specific specialty drugs/medications. The Empire Plan's designated specialty pharmacy is CVS/caremark.

G. **Doctor** means a Doctor of Medicine (M.D.) or a Doctor of Osteopathy (D.O.), who is legally licensed, without limitations, to practice medicine. For benefits provided under this certificate, and for no other purpose, doctor also means a Doctor of Dental Surgery (D.D.S.), a Doctor of Dental Medicine (D.D.M.), a podiatrist and any other health care professional licensed to prescribe medication, when he or she is acting within the scope of his or her license.

H. **Exception** means a request for review of a previous decision made by the Empire Plan Prescription Drug Program that does not involve denial based on medical necessity or as a result of an investigational or experimental use of a covered prescription drug in whole or in part.

I. **Excluded Drug** is a drug that is excluded from coverage under this Program's benefit plan design. This Program will provide no benefit for an excluded drug and you will be responsible for paying the total retail cost of the drug. See the definition for *Medical Exception Process* below for information on how to appeal an excluded drug.

J. **First Fill** means an enrollee's initial or very first dispensing of a specialty drug/medication covered under the Empire Plan Specialty Pharmacy Program.

K. **Flexible Formulary**. In a flexible formulary, brand-name drugs may be assigned to different copayment levels based on value to this Program and clinical judgment. In some cases, drugs may be excluded from coverage if a therapeutic equivalent is covered or available as an over-the-counter drug.

L. **Generic Drug** means a drug sold under its chemical name or sold under a name other than its chemical name by a manufacturer other than the manufacturer that held the original patent for the active ingredient in the drug. The term generic drug shall include authorized generics marketed by or in conjunction with the manufacturer that is the holder of the original patent for the active ingredient of the drug. Any drug approved through an FDA generic drug approval process, including any FDA approval process established for approving generic equivalents of biologic drugs, shall be classified as a generic drug.

M. **Grace Fill for Specialty Drugs** means that an enrollee is allowed to have the first fill of certain specialty drugs/medications dispensed from a pharmacy other than the designated specialty pharmacy. Specialty drugs/medications identified as being for short-term therapy for which a delay in starting therapy would not affect clinical outcome do not have a grace fill.

N. **Mail Service Pharmacy** means all facilities that are owned, operated or affiliated with the Prescription Drug Program administrator to fill enrollee prescriptions for all drugs covered by the Program through the mail service pharmacy. The mail service pharmacy utilized by the Program administrator shall dispense drugs per the terms of this *Certificate* and in accordance with the laws, rules and regulations that govern pharmacy practice.

O. **Medical Exception Process** is a process by which a physician can request a medical necessity review for non-formulary prescription drugs that are excluded from coverage. An appropriate trial of formulary alternatives must be undertaken before a medical exception can be requested.

P. **Medically Necessary Drug** means any drug that, as determined by the Prescription Drug Program administrator, is:

- Provided for the diagnosis or treatment of a medical condition,
- Appropriate for the symptoms, diagnosis or treatment of a medical condition,
- Within the standards of generally accepted health care practice and
- Not used for cosmetic purposes.

If your claim is denied for benefits for a drug or drugs on the basis that the drug is not medically necessary, benefits will be paid under the Empire Plan Prescription Drug Program if the drug is covered under your benefit plan design and:

- Another Empire Plan Program administrator has liability for some portion of the expense related to the administration of that drug being provided to you, has determined the medical necessity of a medical procedure or service provided related to the administration of that drug and has paid benefits in accordance with Empire Plan provisions on your behalf for a medical procedure or service related to the administration of that drug or
- Another Empire Plan Program administrator has liability for some portion of the expense related to the administration of that drug being provided to you, has determined the medical necessity of a medical procedure or service provided related to the administration of that drug and has provided to you a written preauthorization of benefits based on their determination of medical necessity, stating that The Empire Plan benefits will be available to you for a medical procedure or service related to the administration of that drug and
- You provide to the Program proof of payment or preauthorization of benefits from the other Empire Plan Program administrator based on their determination of medical necessity regarding the availability of Empire Plan benefits to you for a medical procedure or service related to the administration of that drug.

In addition, the provisions listed previously do not apply if another Empire Plan administrator paid benefits in error or if the expenses are specifically excluded elsewhere in this *Certificate*.

Q. **Network Pharmacy** means a pharmacy other than a mail service pharmacy or the designated specialty pharmacy that has entered into a contract with the Prescription Drug Program administrator as an independent contractor to dispense drugs per the terms of the contract. It must regularly dispense drugs described in the *What is covered* section, page 113.

R. **No-Fault Motor Vehicle Plan** means a motor vehicle plan that is required by law. It provides medical or dental care payments that are made, in whole or in part, without regard to fault. A person subject to such law who has not complied with the law will be deemed to have received the benefits required by the law.

S. **Non-Network Pharmacy** means any pharmacy, other than a mail service pharmacy, that has not entered into a contract with the Prescription Drug Program administrator to dispense drugs. The enrollee must file a claim form with the Program administrator in order to receive reimbursement for covered drugs received from a non-network pharmacy.

T. **Non-Preferred Drug** means a brand-name drug that is not subject to a Level 1 or Level 2 copayment on the Empire Plan Flexible Formulary drug list.

U. **Pharmacist** means a person who is legally licensed to practice the profession of pharmacy. He or she must regularly practice such profession in a pharmacy.

V. **Pharmacy** means an establishment that is registered as a pharmacy with the appropriate state licensing agency or is a Veterans' Affairs medical center or hospital pharmacy, and regularly dispenses drugs that require a prescription from a doctor. Drugs described in the section *What is covered*, page 113, must be regularly dispensed from the pharmacy by a pharmacist.

W. **Preferred Drug** means a brand-name drug that is subject to a Level 1 or Level 2 copayment on the Empire Plan Flexible Formulary drug list.

X. **Prescription** means the written, oral or electronic request for drugs issued by a provider duly licensed to make such a request in the ordinary course of his or her professional practice. This order must be written in the name of the person for whom it is prescribed or be an authorized refill of that order.

Y. **Prescription Drug Program Administrator** means the company contracted by the State of New York to administer the Empire Plan Prescription Drug Program. The Prescription Drug Program administrator is CVS/caremark. The Program administrator is responsible for processing claims at the level of benefits determined by The Empire Plan and for performing all other administrative functions under the Empire Plan Prescription Drug Program.

Z. **Program** means the Empire Plan Prescription Drug Program described in this *Certificate*.

AA. **Specialty Drugs/Medications** mean drugs that treat rare disease states; require special handling, special administration or intensive patient monitoring/testing; biotech drugs developed from human cell proteins and DNA targeted to treat disease at the cellular level; or other drugs used to treat patients with chronic or life-threatening diseases.

AB. **Therapeutic Category** means categories by which drugs are identified and grouped by the main conditions they treat.

AC. **Therapeutic Equivalent** means prescription drug products that, when compared, can be expected to produce essentially the same therapeutic outcome and toxicity as determined by the Prescription Drug Program administrator.

AD. **Vaccination Network Pharmacy** means an Empire Plan network pharmacy other than a mail service pharmacy or the designated specialty pharmacy that has entered into a contract with the Empire Plan Prescription Drug Program administrator to administer covered seasonal and non-seasonal preventive vaccinations when administered by a licensed pharmacist, or, when authorized by applicable law or regulation, a pharmacy intern.

AE. **Workers' Compensation Law** means a law that requires employees to be covered, at the expense of the employer, for benefits in case they are disabled because of accident or sickness or billed due to a cause connected with their employment.

AF. **You, your or yours** refers to you, the eligible enrollee to whom this *Certificate* is issued. It also refers to your eligible enrolled dependents covered under this Program. For information on eligibility, refer to your *General Information Book*.

The information that follows explains your benefits and responsibilities in detail.

Your Benefits and Responsibilities

Copayments

Copayments for covered drugs are based on the drug, the days' supply and whether the prescription is filled at a network pharmacy, mail service pharmacy or the designated specialty pharmacy. Most Level 1 contraceptive drugs and devices are not subject to copayment.

When you fill your prescription for a covered drug for up to a **30-day supply at a network pharmacy, a mail service pharmacy or the designated specialty pharmacy**, your copayment is:

- **$5** for most **generic** drugs or Level 1 Drugs
- **$25** for **preferred** drugs, compound drugs or Level 2 Drugs
- **$45** for **non-preferred** drugs, certain **generic** drugs or Level 3 Drugs

When you fill your prescription for a **31- to 90-day supply at a network pharmacy**, your copayment is:

- **$10** for most **generic** drugs or Level 1 Drugs
- **$50** for **preferred** drugs, compound drugs or Level 2 Drugs
- **$90** for **non-preferred** drugs, certain **generic** drugs or Level 3 Drugs

When you fill your prescription for a **31- to 90-day supply through a mail service pharmacy or the designated specialty pharmacy**, your copayment is:

- **$5** for most **generic** drugs or Level 1 Drugs
- **$50** for **preferred** drugs, compound drugs or Level 2 Drugs
- **$90** for **non-preferred** drugs, certain **generic** drugs or Level 3 Drugs

Note: Oral chemotherapy drugs for the treatment of cancer do not require a copayment. Generic oral contraceptive drugs and devices or brand-name contraceptive drugs/devices without a generic equivalent (single-source brand-name drugs/devices) do not require a copayment.

Refills are valid for up to one year from the date the prescription is written, subject to applicable state and federal laws.

If the full cost of the drug is less than your copayment, your cost is the lesser amount.

Supply and coverage limits

Certain drugs may be subject to quantity-level limits based on clinical and safety factors related to the dispensing of the drug. Additional clinical quantity-level limits are based on criteria developed by the Prescription Drug Program administrator. The number of days' supply for controlled drugs is in accordance with federal and state mandates.

Erectile dysfunction drugs are limited to a specific quantity-per-day supply: 6 units for a 30-day supply and 7 to 18 units for a 31- to 90-day supply.

Specialty drugs/medications may be dispensed for up to a 90-day supply when clinically appropriate. Certain specialty drugs/medications may only be dispensed for up to a 30-day supply due to clinical/dispensing guidelines.

For certain drugs that have quantity-level limits, additional quantities may be covered through prior authorization. These drugs will be noted with QL/PA on the formulary. Please see *Prior authorization required for certain drugs*, page 112*,* for information on how to request a prior authorization.

Mandatory generic substitution

When your prescription is written dispense as written (DAW) for a brand-name drug that has a generic equivalent, you pay the non-preferred copayment plus the ancillary charge, not to exceed the full retail cost of the drug. When your prescription is not written DAW, in most cases, the generic equivalent is substituted for the brand-name drug and you pay the generic drug copayment.

The following brand-name drugs are excluded from mandatory generic substitution: Coumadin, Dilantin, Lanoxin, Levothroid, Mysoline, Premarin, Synthroid, Tegretol and Tegretol XR. For these drugs, you pay only the applicable copayment, which, in most cases, will be the non-preferred copayment.

Please refer to the *Miscellaneous Provisions* section, page 121, for information regarding the medical exception process for drugs that are excluded from the Flexible Formulary.

If your doctor believes it is medically necessary for you or your family member to have a brand-name drug (that has a generic equivalent), you may appeal the mandatory generic substitution requirement. To begin the appeal process, your doctor should call The Empire Plan and choose the Prescription Drug Program.

Act promptly. If your appeal is approved, upon request, the Prescription Drug Program administrator will adjust claims processed by a pharmacy within 30 days from the date the Program administrator received all information needed to decide the appeal.

If your appeal is granted and you fill your prescription for a brand-name drug at a network pharmacy or through a mail service pharmacy or the designated specialty pharmacy, you pay the non-preferred copayment. If your appeal is denied, you can make a second appeal to the Program administrator.

Empire Plan Flexible Formulary

Under the Empire Plan Flexible Formulary plan design, drugs are classified by therapeutic category or medical condition in order to manage prescription costs without affecting the quality of care. A therapeutic category is a group of drugs that treats a specific health condition or that work in a certain way. For example, antibiotics are used for the treatment of infections.

Drugs on the Empire Plan Flexible Formulary are grouped into levels and your copayment is determined by the "Level" that your medication is on.

- Level 1 drugs have the lowest copayment and include most covered generic drugs and certain brand-name drugs.
- Level 2 drugs have the mid-range copayment and include preferred brand-name drugs that have been selected because of their overall health care value.
- Level 3 drugs have the highest copayment and include non-preferred brand-name drugs and certain generic drugs.

The Flexible Formulary works with the Empire Plan Prescription Drug Program plan design as described here:

- When advantageous to the Plan, the brand-for-generic feature allows a brand-name drug to be placed on Level 1, the lowest copayment level, and the new generic equivalent to be placed on Level 3, the highest copayment level, or excluded. These placements are for a limited time, typically six months, and may be revised mid-year when such changes are advantageous to The Empire Plan.
- Certain therapeutic categories of prescription drugs with two or more clinically sound and therapeutically equivalent Level 1 options may not have a brand-name drug in Level 2.
- Access to one or more drugs in select therapeutic categories may be excluded (not covered) if the drug(s) has no clinical advantage over other generic drug(s) and brand-name drug(s) in the same therapeutic category.

  Drugs considered to have no clinical advantage that may be excluded include any products that:

  - Contain one or more active ingredients available in and therapeutically equivalent to another covered prescription drug in the therapeutic category or in an over-the-counter drug or
  - Contain one or more active ingredients that is a modified version of and therapeutically equivalent to another covered prescription drug or in an over-the-counter drug.

Please refer to the *Exclusions and Limitations* section, page 114, for information about where you can find a list of drugs not covered by the Empire Plan Prescription Drug Program.

New to You prescriptions

For certain maintenance medications, at least two 30-day supplies must be filled using your Empire Plan Prescription Drug Program benefits before a supply for greater than 30 days will be covered. If you attempt to fill a prescription for a new maintenance medication for more than a 30-day supply at a network or mail service pharmacy, the last 180 days of your prescription history will be reviewed to determine whether at least 60 days' worth of the medication has been previously dispensed. If not, only a 30-day fill will be approved.

Prior authorization required for certain drugs

You must have prior authorization to receive Empire Plan Prescription Drug Program benefits for certain drugs. If your doctor prescribes one of these drugs, the Prescription Drug Program administrator will request from your doctor the clinical information required to authorize coverage of the drug. Your doctor may contact the Program administrator to begin the authorization process. The Program administrator and/or pharmacy will notify you of the results of the review. The prior authorization requirements apply whether you use your Empire Plan Benefit Card or will be filing a claim for direct reimbursement.

For a current list of drugs that require prior authorization, visit www.cs.ny.gov. Select Benefit Programs, then NYSHIP Online. Next, choose your group and plan, if prompted. From the NYSHIP Online homepage, select Using Your Benefits and then click on Drugs that Require Prior Authorization.

Certain drugs that require prior authorization based on age, gender or quantity-limit specifications are not listed. Compound drugs that have a claim cost to the Program that exceeds $200 will require prior authorization under this Program. This list of drugs is subject to change. For the most current list of drugs requiring prior authorization and to learn how to obtain prior authorization, call The Empire Plan and choose the Empire Plan Prescription Drug Program or visit our website (see *Contact Information*, page 130).

If the prior authorization review results in authorization for payment, you will receive Prescription Drug Program benefits for the drug. If the payment is not authorized, no Prescription Drug Program benefits will be paid for the drug.

An appeal process allows you or your doctor to ask for further review if authorization is not granted. You may call The Empire Plan and choose the Prescription Drug Program for information on how to initiate an appeal.

Specialty Pharmacy Program

Under the Empire Plan Specialty Pharmacy Program, when your physician prescribes a covered specialty drug/medication, you may be directed to the designated specialty pharmacy to obtain benefits under the Program.

The Program requires certain specialty drugs/medications to be dispensed by the designated specialty pharmacy. When initiating therapy with a specialty drug/medication, you may send the prescription directly to the designated specialty pharmacy to start receiving Specialty Pharmacy Program benefits. Otherwise, you are allowed one grace fill for specialty drugs, during which time the Program will cover the first fill of your medication at any network pharmacy with the applicable copayment. (Specialty drugs/medications identified as being for short-term therapy, for which a delay in starting therapy would not affect clinical outcome [e.g., drugs needed for the treatment of Hepatitis C], do not have a grace fill.)

After your first fill, you are covered for subsequent fills of your specialty drug/medication when dispensed by the designated specialty pharmacy. You will be charged the mail service copayment for covered specialty drugs/medications dispensed by the designated specialty pharmacy.

The Empire Plan Specialty Drug/Medication list is subject to change without notice. To view the most current list, go to the NYS Department of Civil Service website or call the Empire Plan Prescription Drug Program (see *Contact Information*, page 130).

If you pay the full cost of your specialty drug/medication at a pharmacy other than the designated specialty pharmacy, you will be required to file a claim for reimbursement. You will not be reimbursed the total amount you paid for the prescription and you will be responsible for the difference between the amount charged and amount you are reimbursed under this Program. Your out-of-pocket expense may exceed the usual mail service copayment amount.

What is covered

You are covered for the following prescription drugs or medicines when they are covered under this Program's benefit design, are medically necessary and are dispensed by a pharmacy:

A. FDA-approved drugs that must bear the legend "Rx Only."

B. State-restricted drugs (drugs or medicines that can be dispensed in accordance with New York State law [or by the laws of the state or jurisdiction in which the prescription is filled] by prescription only).

C. Compound drug(s)/medication(s).

D. Injectable insulin.

E. First fill of a specialty drug/medication filled at a network, non-network or mail service pharmacy and subsequent fills processed by the designated specialty pharmacy. Specialty drugs/medications identified as being for short-term therapy, for which a delay in starting therapy would not affect clinical outcome (e.g., drugs needed for the treatment of Hepatitis C), do not have a grace fill.

F. Oral, injectable or surgically implanted contraceptives that bear the legend "Rx Only;" diaphragms; and contraceptive devices.

G. Vitamins that are FDA-approved prescription drugs and bear the legend "Rx Only."

H. Covered prescription drugs dispensed by on-premises pharmacies to patients in a skilled nursing facility, rest home, sanitarium, extended care facility, convalescent hospital or similar facility. Such on-premises pharmacies are considered non-network pharmacies and require submission of a claim form for reimbursement.

I. Claims for drugs dispensed outside of the United States that have an available U.S. FDA-approved equivalent.

J. Orally administered anti-cancer medication used to kill or slow the growth of cancerous cells.

K. Off-label cancer drugs.

L. Smoking cessation drugs, including over-the-counter drugs for which there is a written order, and prescription drugs prescribed by a physician or other provider.

M. Certain preventive vaccinations in accordance with the Affordable Care Act (ACA) mandates, administered at a vaccination network pharmacy, will be covered at no cost. The covered preventive vaccines are: influenza – flu, pneumococcal – pneumonia, meningococcal – meningitis and herpes zoster* – shingles.

* The zero copayment benefit for the herpes zoster vaccine is for individuals age 60 and older. The immunization is covered for individuals ages 55 to 59 at the Level 1 copayment.

Please refer to the following section, *Exclusions and Limitations*, for conditions under which benefits are not available.

Exclusions and Limitations

Charges for the following items are **not** covered expenses:

A. Drugs obtained with no prescription order, including over-the-counter products (except insulin, smoking cessation drugs and over-the-counter preventive drugs or devices provided in accordance with guidelines supported by the Health Resources and Services Administration or with an "A" or "B" rating from the United States Preventive Services Task Force).

B. Drugs taken or given at the time and place of the prescription order and billed by the doctor.

C. Drugs provided or required by any governmental program or statute (other than Medicaid) unless there is a legal obligation to pay.

D. Drugs for which there is no charge or legal obligation to pay in the absence of insurance.

E. Drugs administered to you by the facility while a patient in a licensed hospital. This limit applies only if the hospital in which you are a patient operates on its premises, or allows to be operated on its premises, a facility that dispenses pharmaceuticals and dispenses such drugs administered to you by the hospital.

F. Any drug refill that is more than the number approved by the doctor.

G. Therapeutic devices or appliances (e.g., hypodermic needles, syringes, support garments or other non-medicinal substances), regardless of their intended use.

H. The administration of any drug or injectable insulin, with the exception of covered preventive vaccines administered at a vaccination network pharmacy.

I. Any drug refill that is dispensed more than one year after the original date of the prescription order, subject to applicable state and federal laws.

J. Any drug labeled "Caution: Limited by Federal Law to Investigational Use," or experimental drugs except for drugs used for the treatment of cancer as specified in Section 3221(k)12 of New York

State Insurance Law as may be amended from time to time. Prescribed drugs approved by the U.S. Food and Drug Administration for the treatment of certain types of cancer shall not be excluded when the drug has been prescribed for another type of cancer. However, coverage shall not be provided for experimental or investigational drugs or any drug that the U.S. Food and Drug Administration has determined to be contraindicated for treatment of the specific type of cancer for which the drug has been prescribed.

Experimental or investigational drugs shall also be covered when approved by an external appeal agent in accordance with an external appeal. For external appeal provisions, see *Your right to an external appeal*, page 124. If the external appeal agent approves coverage of an experimental or investigational drug that is part of a clinical trial, only the costs of the drug will be covered. Coverage will not be provided for the costs of experimental or investigational drugs or devices, the costs of nonhealth-care services, the costs of managing research or costs not otherwise covered by The Empire Plan for nonexperimental or noninvestigational drugs provided in connection with such clinical trial.

K. Immunizing agents, with the exception of covered preventive vaccinations administered at a vaccination network pharmacy, biological sera, blood or blood plasma, except immune globulin.

L. Any drug that a doctor or other health professional is not authorized by his or her license to prescribe.

M. Drugs for an injury or sickness related to employment for which benefits are provided by any state or federal workers' compensation, employers' liability or occupational disease law or under Medicare or other governmental program, except Medicaid.

N. Drugs purchased prior to the start of coverage or after coverage ends. However, if the person is totally disabled on the date this insurance ends, see *Benefits after termination of coverage*, page 121.

O. Any drug prescribed and/or dispensed in violation of state or federal law.

P. Prescription drug products excluded from the benefit plan design. For a current list of excluded drugs, visit www.cs.ny.gov. Select Benefit Programs, then NYSHIP Online. Next, choose your group and plan, if prompted. From the NYSHIP Online homepage, select Using Your Benefits and then click on the Excluded Drug List.

Q. New prescription drug products that are in the same therapeutic category as existing drugs excluded under the Empire Plan Flexible Formulary or that are in the same therapeutic category as drugs excluded from benefit coverage under this Plan. Please refer to the New York State Department of Civil Service website or call the Empire Plan Prescription Drug Program (see *Contact Information*, page 130) for current information regarding exclusions of newly launched prescription drugs.

R. Drugs furnished solely for the purpose of improving appearance rather than physical function or control of organic disease, which include but are not limited to:

- Anorexiants, except for morbid obesity.
- Products used to promote hair growth.
- Products (for example, Retinoic Acid) used for prevention of skin wrinkling.

S. Coverage for drugs where the amount dispensed exceeds the supply limit.

T. Coverage for drugs as a replacement for a previously dispensed drug.

U. Products for which the primary use is nutrition.

V. Any non-medically necessary drugs.

W. Claims for foreign drugs for which there is no available U.S. equivalent approved by the FDA.

IMPORTANT: See your *General Information Book* for other conditions that may affect this coverage. See the *Home Care Advocacy Program (HCAP)* section of your *Medical/Surgical Program Certificate*, page 57, for coverage for prescription drugs billed by a home care agency.

How to Use Your Empire Plan Prescription Drug Program

When your doctor prescribes a medically necessary drug covered under The Empire Plan, you can fill the prescription for a supply of up to 90 days and refills for up to one year, subject to applicable state and federal laws, in one of four ways: at a network pharmacy, at a non-network pharmacy, through a mail service pharmacy or through the designated specialty pharmacy.

When your doctor starts you on a new drug, you may want to have your prescription filled for a 30-day supply to ensure the prescription is right for your condition.

Network pharmacies and vaccination network pharmacies

You can use your Empire Plan Benefit Card for covered prescription drugs at Empire Plan network pharmacies. All Empire Plan network pharmacies can fill prescriptions for supplies of up to 90 days. Refills of covered drugs are provided for up to a year from the date the prescription is written, subject to applicable state and federal laws. Only one copayment applies for up to a 90-day supply.

You may also use your Empire Plan Benefit Card for covered preventive vaccinations (see item M. in *What is covered*, page 114) administered at Empire Plan vaccination network pharmacies. Not all Empire Plan vaccination network pharmacies stock all of the covered preventive vaccines, and some may also decline to provide vaccinations to minors based on state law or clinical considerations. It is advised that you call the pharmacy to confirm participation and availability of specific vaccines. Many retail pharmacies in New York State participate in this Program. Many out-of-state pharmacies participate as well.

Be sure your pharmacist knows that you and your family have Empire Plan Prescription Drug Program coverage when you submit your prescriptions or receive a vaccination.

To find a network pharmacy or vaccination network pharmacy, check with your pharmacist, call The Empire Plan and choose the Empire Plan Prescription Drug Program, or visit the website (see the *Contact Information* section, page 130).

Non-network pharmacies

You can use a non-network pharmacy or pay the full amount for your prescription at a network pharmacy (instead of using your Empire Plan Benefit Card) and fill out a claim for reimbursement.

In almost all cases, you will not be reimbursed the total amount you paid for the prescription and your out-of-pocket expenses may exceed the usual copayment amount. To reduce your out-of-pocket expenses, use your Empire Plan Benefit Card whenever possible.

Out-of-Pocket Expenses: When you use a non-network pharmacy or pay the full amount for your prescription at a network pharmacy, you are responsible for the difference between the amount charged and the amount you are reimbursed under this Program.

For claim forms, call The Empire Plan and choose the Empire Plan Prescription Drug Program or download one from the website (see *Contact Information*, page 130).

Mail the completed form with your bills or receipts to the Empire Plan Prescription Drug Program (see *Contact Information*).

Several factors affect the amount of your reimbursement:

- If your prescription was filled with a generic drug, a brand-name drug with no generic equivalent or insulin, you will be reimbursed up to the amount this Program would reimburse a network pharmacy for that prescription as calculated using the Program's standard reimbursement rate for network pharmacies, less the applicable copayment.
- If your prescription was filled with a brand-name drug with a generic equivalent (other than drugs excluded from mandatory generic substitution), you will be reimbursed up to the amount this Program would reimburse a network pharmacy for filling the prescription with that drug's generic equivalent as calculated using the Program's standard reimbursement rates for network pharmacies, less the applicable copayment (in most cases, that will be the non-preferred copayment).

- Any covered preventive vaccination administered in a pharmacy other than an Empire Plan vaccination network pharmacy will be covered as a non-network claim under the Empire Plan Medical/Surgical Program.

Please refer to the *Medical/Surgical Program Certificate of Insurance* for non-network claim reimbursement instructions.

Deadline for filing claims

Claims must be submitted within 120 days after the end of the calendar year in which the prescription drugs were purchased, or 120 days after another plan processes your claim, whichever is later, unless it was not reasonably possible for you to meet this deadline (for example, due to your illness).

Mail service pharmacy or the designated specialty pharmacy

All drugs covered by the Program can be ordered through a mail service pharmacy or the designated specialty pharmacy.

You can order and receive up to a 90-day supply of your prescriptions, shipped by first-class mail or private carrier. You can pay your copayment(s) and other costs by credit card, check or money order. To request mail service envelopes, refills or to speak to a pharmacist about your mail service prescription, call The Empire Plan and choose the Empire Plan Prescription Drug Program, 24 hours a day, seven days a week (see *Contact Information*, page 130). The mail service pharmacy or the designated specialty pharmacy address is also listed here.

Using the Empire Plan Flexible Formulary drug list

One way you can help control the rapidly increasing cost of prescription drugs is to encourage your doctor(s) to prescribe and pharmacist to dispense covered generic and preferred drugs listed on the Empire Plan Flexible Formulary drug list. (The Empire Plan Flexible Formulary drug list is available on NYSHIP Online; see *Contact Information*.) This is not a complete list of all prescription drugs on the Flexible Formulary or covered under The Empire Plan. This list and excluded medications are subject to change. New prescription drugs may be subject to exclusion when they become available in the market.

This list provides the most commonly prescribed generic and brand-name drugs included on the Empire Plan Flexible Formulary drug list. These drugs are safe and effective alternatives to higher-cost drugs. Using prescription drugs that appear on this list will save you money. Using generics will save you even more.

The Plan will provide the Flexible Formulary drug list to you and to Empire Plan participating doctors. Doctors are encouraged—but not required—to use this list.

Remember, if your doctor prescribes a prescription drug that is excluded from coverage under The Empire Plan benefit plan design, you will pay the full retail cost for your prescription. See *Medical exception process for drugs excluded from the Flexible Formulary*, page 122.

Help control the rising cost of the prescription drug program by asking your doctor to prescribe a covered drug that is appropriate for you from the Flexible Formulary drug list.

Coverage for preventive vaccines administered in a vaccination network pharmacy

Empire Plan-primary enrollees and dependents may obtain seasonal and non-seasonal preventive vaccines administered at a vaccination network pharmacy with no copayment in accordance with the Patient Protection and Affordable Care Act (PPACA) mandates. The following preventive vaccines are covered: influenza – flu, pneumococcal – pneumonia, meningococcal – meningitis and herpes zoster – shingles.

Notes:

- New York State restricts pharmacists from administering vaccines to anyone younger than 18. Regulations regarding age limits may differ by state.
- New York State requires a prescription for the herpes zoster vaccine.
- The no-copayment benefit for the herpes zoster vaccine is applicable to enrollees and dependents age 60 or older (as per PPACA recommendations). The herpes zoster vaccine is also available to enrollees and dependents between the ages of 55 and 59, subject to the Level 1, 30-day supply copayment.
- Medicare-primary enrollees and dependents already have coverage for these vaccines in a pharmacy setting under Medicare Parts B and D.

Contact the Empire Plan Prescription Drug Program

For questions about your Empire Plan Prescription Drug Program, call The Empire Plan and choose the Empire Plan Prescription Drug Program.

Call 24 hours a day, seven days a week if you need to:

- Verify your eligibility.
- Find out if your claims have been paid.
- Locate an Empire Plan network pharmacy.
- Order refills from a mail service pharmacy or the designated specialty pharmacy or check order status.
- Talk to a customer service representative.
- Request prior authorization or a generic appeal.
- Talk to a pharmacist.

Visit NYSHIP Online. Then choose Find a Provider and scroll to the Prescription Drug Program links if you need to:

- Locate an Empire Plan network pharmacy.
- Order refills online from the mail order pharmacy or check order status.
- Order refills online from the designated specialty pharmacy and check order status.
- Download a mail service pharmacy order form.
- View the list of drugs subject to prior authorization.
- View the Flexible Formulary drug list.

Coordination of Benefits (COB)

A. **Coordination of Benefits** means that the benefits provided for you under the Empire Plan Prescription Drug Program are coordinated with the benefits provided for you under another group plan. The purpose of coordination of benefits is to avoid duplicate benefit payments so that the total payment under The Empire Plan and under another plan is not more than the total allowable charge for a service covered under both group plans.

   If a covered drug is submitted under the Program, the Program will reimburse the enrollee the submitted balance or the amount that would have been paid as a network benefit under The Empire Plan, whichever is lower. In addition, if you or any of your dependent(s) are covered under two separate Empire Plan policies, you may use a claim form to submit Empire Plan copayments for reimbursement under your secondary Empire Plan coverage.

B. Definitions

- **Plan** means a plan that provides benefits or services for or by reason of medical or dental care and that is one of the following:
  - A group insurance plan.
  - A blanket plan, except for blanket school accident coverages or such coverages issued to a substantially similar group where the policyholder pays the premium.
  - A self-insured or noninsured plan.
  - Any other plan arranged through any employee, trustee, union, employer organization or employee benefit organization.
  - A group service plan.
  - A group prepayment plan.
  - Any other plan that covers people as a group.
  - A governmental program or coverage required or provided by any law except Medicaid or a law or plan when, by law, its benefits are excess to those of any private insurance plan or other nongovernmental plan.
- **Order of Benefit Determination** means the procedure used to decide which plan will determine its benefits before any other plan. Each policy, contract or other arrangement for benefits or services will be treated as a separate plan. Each part of The Empire Plan that reserves the right to take the benefits or services of other plans into account to determine its benefits will be treated separately from those parts that do not.

C. When coordination of benefits applies and The Empire Plan is secondary, payment under The Empire Plan will be reduced so that the total of all payments or benefits payable under The Empire Plan and under another plan is not more than the total allowable charge for the service you receive.

D. Payments under The Empire Plan will not be reduced on account of benefits payable under another plan if the other plan has a coordination of benefits or similar provision with the same order of benefit determination as stated in item E., and under that order of benefit determination, the benefits under The Empire Plan are to be determined before the benefits under the other plan.

E. When more than one plan covers the person making the claim, the order of benefit payment is determined using the first of the following rules that applies:

1. The benefits of the plan that covers the person as an enrollee are determined before those of other plans that cover that person as a dependent.
2. When this Plan and another plan cover the same child as a dependent of different persons called "parents" and the parents are not divorced or separated. (For coverage of a dependent of parents who are divorced or separated see item 3.):
   - The benefits of the plan of the parent whose birthday falls earlier in the year are determined before those of the plan of the parent whose birthday falls later in the year but
   - If both parents have the same birthday, the benefits of the plan that has covered one parent for a longer period of time are determined before those of the plan that has covered the other parent for the shorter period of time.
   - If the other plan does not have the rule described in the preceding two subparagraphs, but instead has a rule based on gender of the parent, and if, as a result, the plans do not agree on the order of benefits, the rule in the other plan will determine the order of benefits.
   - The word birthday refers only to month and day in a calendar year, not the year in which the person was born.

3. If two or more plans cover a person as a dependent child of divorced or separated parents, benefits for the child are determined in this order:
   - First, the plan of the parent with custody of the child.
   - Then, the plan of the spouse of the parent with custody of the child.
   - Finally, the plan of the parent not having custody of the child.
   - If the specific terms of a court decree state that one of the parents is responsible for the health care expenses of the child, and the entity obligated to pay or provide the benefits of the plan of that parent has actual knowledge of those terms, the benefits of that plan are determined first. This paragraph does not apply to any benefits paid or provided before the entity had such knowledge.
4. The benefits of a plan that covers a person as an employee or as the dependent of an employee who is neither laid-off nor retired are determined before those of a plan that covers that person as a laid-off or retired employee or as the dependent of such an employee. If the other plan does not have this rule and if as a result the plans do not agree on the order of benefits, this rule (4.) is ignored.
5. If none of the rules in 1. through 4. determined the order of benefits, the plan that has covered the person for the longest period of time determines its benefits first.

F. For the purpose of applying this provision, if both spouses/domestic partners are covered as employees under The Empire Plan, each spouse/domestic partner will be considered as covered under separate plans.

G. Any information about covered expenses and benefits that is needed to apply this provision may be given or received without the consent of or notice to any person, except as required by Article 25 of the General Business Law.

H. If an overpayment is made under The Empire Plan before it is learned that you also had other coverage, there is a right to recover the overpayment. You will have to refund the amount by which the benefits paid on your behalf should have been reduced. In most cases, this will be the amount that was received from the other plan.

I. If payments that should have been made under The Empire Plan have been made under other plans, the party that made the other payments will have the right to receive any amounts that are considered proper under this provision.

Medicare Prescription Drug Coverage

NYSHIP replaced the Empire Plan Prescription Drug Program coverage for Medicare-primary enrollees and Medicare-primary dependents with Empire Plan Medicare Rx (PDP), a Medicare Part D prescription drug program with expanded coverage designed especially for NYSHIP.

This prescription drug coverage is administered by CVS/caremark. Eligible individuals are enrolled automatically in Empire Plan Medicare Rx. Prior to enrollment, affected enrollees and dependents will receive important plan benefit information from the New York State Department of Civil Service and the Prescription Drug Program administrator. No action is required by you to enroll in Empire Plan Medicare Rx and keep your Empire Plan coverage.

If you are Medicare primary, you must be enrolled in Empire Plan Medicare Rx. If you cancel your enrollment in Empire Plan Medicare Rx, your Empire Plan coverage also will be canceled for Hospital, Medical/Surgical and Mental Health and Substance Abuse benefits.

Note: Please refer to your *Evidence of Coverage* and *Empire Plan Medicare Rx (PDP) Plus Certificate* regarding secondary coverage benefits.

Miscellaneous Provisions

Termination of coverage

A. Coverage will end when you are no longer eligible to participate in this Program. Refer to the eligibility section of your *General Information Book*.

   Under certain conditions, you may be eligible to continue coverage under The Empire Plan temporarily after eligibility ends. Refer to the COBRA section of your *General Information Book*.

B. If this Program ends, your Program coverage will end.

C. Coverage of a dependent will end on the date that dependent ceases to be a dependent as defined in your *General Information Book*.

   Under certain conditions, dependent(s) of employees or former employees may be eligible to continue coverage under The Empire Plan temporarily after eligibility ends. Refer to the COBRA section of your *General Information Book*.

D. If a payment that is required from you toward the cost of The Empire Plan coverage is not made, the coverage will end on the last day of the period for which a payment was made.

E. If coverage ends, any claim incurred before your coverage ends for any reason will not be affected; also, see *Benefits after termination of coverage*.

Benefits after termination of coverage

You may be totally disabled on the date coverage ends on your account. If so, benefits will be provided to treat the condition that caused the total disability on the same basis as if coverage had continued with no change until the date you are no longer totally disabled or for up to 12 months from the date your coverage ends, whichever is earlier. This does not apply if the services are covered under another group health plan or Medicare.

Totally Disabled means that because of a sickness or injury you, the enrollee, cannot do your job, or any other work for which you might be trained, or your dependent cannot do his or her usual duties.

Call the Prescription Drug Program administrator if you need more information about benefits after termination of coverage.

Recovery of overpayments and subrogation

Recovery of overpayments

On occasion, a payment will be made to you when you are not covered, for a service that is not covered, or in an amount that is more than proper. When this happens, the problem will be explained to you and you must return the amount of the overpayment within 60 days after receiving notification.

Right to offset

If the Prescription Drug Program makes a claim payment to you or on your behalf in error or you owe the Program money, you must repay the amount owed. Except as otherwise required by law, if the Prescription Drug Program owes you a payment for other claims received, the Program has the right to subtract any amount owed by you from any payment owed to you.

Subrogation and reimbursement

These paragraphs apply when another party (including another insurer) is, or may be found to be, responsible for your injury, illness or other condition and the Program has provided benefits related to that injury, illness or other condition. As permitted by applicable state law (unless preempted by federal law), the Prescription Drug Program may be subrogated to all rights of recovery against such party (including your own insurance carrier) for the benefits provided to you under this *Certificate*. Subrogation means that the Program has the right, independently of you, to proceed directly against the other party to recover the benefits the Program provided.

Subject to applicable state law (unless preempted by federal law), the Program may have the right to reimbursement if you or anyone on your behalf receives payment from any responsible party (including your own insurance carrier) from any settlement, verdict or insurance proceeds, in connection with an injury, illness or condition for which the Prescription Drug Program provided benefits. Under Section 5-335 of the New York General Obligations Law, the Program's right of recovery does not apply when a settlement is reached between a plaintiff and a defendant, unless a statutory right of reimbursement exists. The law also provides that, when entering into a settlement, it is presumed that you did not take any action against the Program's rights or violate any contract between you and the Program. The law presumes that the settlement between you and the responsible party does not include compensation for the cost of health care services for which the Prescription Drug Program provided benefits.

The Prescription Drug Program requests that you notify them within 30 days of the date when any notice is given to any party, including an insurance company or attorney, of your intention to pursue or investigate a claim to recover damages or to obtain compensation due to an injury, illness or condition sustained by you for which the Prescription Drug Program provided benefits. You must provide all information requested by the Program or the Program's representatives including, but not limited to, completing and submitting any applications or other forms or statements as the Program reasonably requests.

Audits/prescription benefit records

From time to time, the Prescription Drug Program administrator may ask you to verify receipt of particular drugs from network pharmacies or from a mail service pharmacy or the designated specialty pharmacy. These requests are part of the auditing process. Your cooperation may be helpful in identifying fraudulent practices or unnecessary charges to your plan. All such personal information will remain confidential.

Legal action

Lawsuits to obtain benefits may not be started less than 60 days or more than two years following the date you receive written notice that benefits have been denied.

Medical exception process for drugs excluded from the Flexible Formulary (for non-Medicare-primary enrollees)

The Empire Plan includes a medical exception process for non-formulary prescription drugs that are excluded from coverage. Enrollees and their physicians must first evaluate whether covered drugs on the Flexible Formulary are appropriate alternatives for their treatment. After an appropriate trial of formulary alternatives, an enrollee's physician may submit a letter of medical necessity to the Empire Plan Prescription Drug Program administrator, which details the enrollee's formulary alternative trials and any other clinical documentation supporting medical necessity. The physician can fax the exception request (see the *Contact Information* section, page 130, for details). If an exception is approved, the Level 1 copayment will apply for generic drugs and the Level 3 copayment (and ancillary charge, if applicable) will apply for brand-name drugs.

Note: Drugs that are only FDA approved for cosmetic indications are excluded from the Plan and are not eligible for a medical exception.

Appeals

You or another person acting on your behalf may submit an appeal. If a post-service claim (a claim for benefits payment after a prescription drug has been dispensed) or a preservice request for benefits is denied in whole or in part, two levels of appeal are available to you. You may submit an appeal in writing to the Empire Plan Prescription Drug Program (see *Contact Information*, page 130).

Call The Empire Plan and choose the Prescription Drug Program.

Appeal process

A qualified individual who was not involved in the decision being appealed will be appointed to decide the appeal. By filing an appeal, you consent to this referral and the sharing of pertinent claims information.

First-level claims review

In the event a claim has been denied, as not medically necessary or as a result of investigational or experimental use of a covered prescription drug, you can request a review of your claim. This request for review should be sent to the Claims Review Unit at the Empire Plan Prescription Drug Program address (see *Contact Information*, page 130) within 180 days after you receive notice of denial of the claim. When requesting a review, please state the reason you believe the claim was improperly denied and submit any data or comments to support the appeal of the original determination as well as any information that has been requested. A written acknowledgment of your appeal will be sent to you within 15 days after it is received.

For a first-level appeal, the following timeframes apply:

- **Preservice claims** are requests that services or treatments be approved before they have been received. A preservice claim appeal determination is made within 15 days of receipt of the claim appeal and all necessary information.
- **Post-service claims** are requests for services or treatments that have already been received. A post-service claim appeal determination is made within 30 days of receipt of the claim and all necessary information.
- **Expedited/urgent appeal determinations** are made the earlier of two business days of receipt of all necessary information or 72 hours of receipt of your claim appeal.

If the determination is upheld, the Program administrator's written response will cite the specific Plan provision(s) upon which the denial is based and will include both of the following:

- Detailed reasons for the determination regarding the appeal and the rationale for the determination.
- Notification of your right to a further review (if applicable).

Second-level claims review

If, as a result of the first-level claims review, the original determination of benefits is upheld by the Prescription Drug administrator, in whole or in part, you can request a second-level claims review. A second-level appeal is a voluntary step in the claims review process, and you are **not** required to complete this step before seeking an external appeal. This request should be directed either in writing or by telephone to the Program administrator within 60 days after you receive notice of the first-level appeal determination. When requesting the second-level claims review, you should state the reasons you believe the benefit reduction or denial was improperly upheld and include any information requested by the Program administrator along with any additional data, questions or comments deemed appropriate.

For a second-level appeal, the following timeframes apply:

- **Preservice claims** are requests that services or treatments be approved before they have been received. A preservice claim appeal determination is made within 15 days of receipt of the claim appeal and all necessary information.
- **Post-service claims** are requests for services or treatments that have already been received. A post-service claim appeal determination is made within 30 days of receipt of the claim and all necessary information.

If an appeal involves a clinical matter, appropriate clinical staff as required by New York State law will be responsible for ensuring the appeal is reviewed by an appropriate provider who did not previously review the claim or precertification request. If an appeal involves an administrative matter, it will be reviewed by another employee of the Prescription Drug Program administrator.

If the determination is upheld, the Program administrator's written response will cite the specific Plan provision(s) upon which the denial is based and will provide detailed reasons for the determination regarding the appeal. If the case involves a clinical matter, the clinical rationale for the determination will be given.

Appeals involving urgent situations

If an appeal involves a situation in which your provider believes a delay would significantly increase the risk to your health or the ability to regain maximum function, or cause severe pain, the appeal will be resolved in no more than 72 hours from receipt of the appeal. Notice of the determination will be made directly to the person filing the appeal (you or the person acting on your behalf).

If you are unable to resolve a problem with an Empire Plan Program administrator, you may contact the Consumer Assistance Unit of the New York State Department of Financial Services (see *Contact Information*, page 131).

External appeals

Your right to an external appeal

Under certain circumstances, you have a right to an external appeal of a denial of coverage. Specifically, if the Prescription Drug Program administrator has denied coverage on the basis that a prescription drug is not medically necessary or is an experimental or investigational drug, you or your representative may appeal for review of that decision by an external appeal agent, an independent entity certified by the New York State Department of Financial Services to conduct such appeals.

Your right to appeal a determination that a drug is not medically necessary

If you have been denied coverage on the basis that the prescription drug is not medically necessary, you may appeal for review by an external appeal agent if you satisfy the following two criteria:

- The prescription drug must otherwise be covered under the Empire Plan Prescription Drug Program.
- You must have received a final adverse determination through the internal appeal process described previously and the Program administrator must have upheld the denial or you both must agree in writing to waive any internal appeal.

Your right to appeal a determination that a drug is experimental or investigational

If you have been denied coverage on the basis that the drug is experimental or investigational, you must satisfy the following two criteria:

- The prescription drug must otherwise be covered under the Empire Plan Prescription Drug Program.
- You must have received a final adverse determination through the internal appeal process described previously and, if any new or additional information regarding the prescription drug was presented for consideration, the Prescription Drug Program administrator must have upheld the denial or you both must agree in writing to waive any internal appeal.

Your attending physician must certify that you have a condition/disease: a.) whereby standard covered prescription drugs have been ineffective or would be medically inappropriate, b.) for which there does not exist a more beneficial standard prescription drug covered by the health care plan or c.) for which there exists a clinical trial or rare disease treatment.

In addition, your attending physician must have recommended one of the following:

- A drug that two documents from available medical and scientific evidence indicate is likely to be more beneficial to you than any standard covered drug (only certain documents will be considered in support of this recommendation. Your attending physician should contact the New York State Department of Financial Services to obtain current information about what documents will be considered acceptable).
- A clinical trial for which you are eligible (only certain clinical trials can be considered).

For the purposes of this section, your attending physician must be a licensed, board-certified or board-eligible physician qualified to practice in the area appropriate to treat your condition or disease.

Your right to appeal that a prescription drug should be covered because you have been diagnosed with what is considered a rare disease

A rare disease is defined as a condition:

- That is currently or has been subject to a research study by the National Institutes of Health Rare Disease Clinical Network or affects fewer than 200,000 United States residents per year and
- For which there are no standard prescription drugs covered by the health care plan that are more clinically beneficial than the requested prescription drug.

As part of the external appeal process for rare diseases, a physician other than the member's treating physician must certify in writing that the condition is a rare disease. The certifying physician must be a licensed, board-certified or board-eligible physician specializing in the appropriate area of practice to treat the rare disease. The physician's certification must provide either that:

- The rare disease is or has been subject to a research study by the National Institutes of Health Rare Disease Clinical Research Network or
- The rare disease affects fewer than 200,000 United States residents per year.

The certification is to rely on medical and scientific evidence to support the requested prescription drug (if such evidence exists) and must include a statement that, based on the physician's credible experience, there is no standard covered prescription drug that will be more clinically beneficial to the member. The statement must also indicate that the requested prescription drug is likely to benefit the member in the treatment of the rare disease and that the benefit outweighs the risks of the prescription drug.

The external appeal process

If, through the internal appeal process described previously, you have received a final adverse determination upholding a denial of coverage on the basis that the prescription drug is not medically necessary or is an experimental or investigational drug, you have four months from receipt of such notice to file a written request for an external appeal. If you and the Program administrator have agreed in writing to waive any internal appeal, you have four months from receipt of such waiver to file a written request for an external appeal. The Program administrator will provide an external appeal application with the final adverse determination issued through its internal appeal process described previously or its written waiver of an internal appeal. You may also request an external appeal application from the New York State Department of Financial Services (see *Contact Information*, page 131). Submit the completed application to the Department of Financial Services at the address indicated on the application. If you satisfy the criteria for an external appeal, the Department of Financial Services will forward the request to a certified external appeal agent.

You will have an opportunity to submit additional documentation with your request. If the external appeal agent determines that the information you submit represents a material change from the information on which the Program administrator based its denial, the external appeal agent will share this information with the administrator in order for it to exercise its right to reconsider its decision. If the administrator chooses to exercise this right, it will have three business days to amend or confirm its decision. Please note that in the case of an expedited appeal (described in the following), the administrator does not have a right to reconsider its decision.

In general, the external appeal agent must make a decision within 30 days of receipt of your completed application. The external appeal agent may request additional information from you, your doctor or the Program administrator. If the external appeal agent requests additional information, it will have five additional business days to make its decision. The external appeal agent must then notify you in writing of its decision within two business days.

If your attending doctor certifies that a delay in providing the prescription drug that has been denied poses an imminent or serious threat to your health, you may request an expedited external appeal. In that case, the external appeal agent must make a decision within 72 hours of receipt of your completed application. Immediately after reaching a decision, the external appeal agent must try to notify you and the Program administrator by telephone or facsimile of that decision. The external appeal agent must also notify you in writing of its decision. If the external appeal agent overturns the Program administrator's decision that a service is not medically necessary or approves coverage of an experimental or investigational drug, the Plan will provide coverage subject to the other terms and conditions of the Program.

Please note that if the external appeal agent approves coverage of an experimental or investigational prescription drug that is part of a clinical trial, the Plan will only cover the costs of the prescription drug required to provide treatment to you according to the design of the trial. The Plan shall not be responsible for the costs of investigational devices, the costs of nonhealth-care services, the costs of managing research or costs that would not be covered under the Policy for nonexperimental or noninvestigational treatments provided in such clinical trial.

The external appeal agent's decision is binding on both parties. The external appeal agent's decision is admissible in any court proceeding.

You will be charged a fee of $25 for an external appeal, and the annual limit on filing fees for a claimant within a single year will not exceed $75. The external appeal application will instruct you on the manner in which you must submit the fee and the fee will be waived if it is determined that paying it would pose a hardship to you. If the external appeal agent overturns the denial of coverage, the fee shall be refunded to you.

Your responsibilities in filing an external appeal

It is **YOUR RESPONSIBILITY** to initiate the external appeal process. You may initiate the external appeal process by filing a completed application with the New York State Department of Financial Services. If the requested service has already been provided to you, your doctor may file an external appeal application on your behalf, but only if you have consented to this in writing.

Four-month external appeal deadline

Under New York State law, your completed request for external appeal must be received by the New York State Department of Financial Services within four months (with an additional eight days allowed for mailing) of the date of the final notice of adverse determination of the first-level appeal or the date upon which you receive a written waiver of any internal appeal. The Prescription Drug Program administrator has no authority to grant an extension of this deadline.

Empire Plan Prescription Drug Program Drug Utilization Review (DUR)

Prescription drugs can cure ailments and keep you healthy—often at a cost much lower than surgery or other procedures. They can, however, also cause serious harm when taken in the wrong dosage or in a harmful combination with another drug.

Your Empire Plan Prescription Drug Program includes a drug utilization review (DUR) Program to check for possible inappropriate drug consumption, medical conflicts or dangerous drug interactions.

This review process generally asks:

- Is the prescription written for the recommended daily dose?
- Is the patient already taking another drug that might conflict with the newly prescribed drug?
- Does the patient's prescription drug record indicate a medical condition that might be made worse by this drug?
- Has the age of the patient been taken into account in prescribing this drug?
- Is the patient taking a quantity of the drug that is consistent with the doctor's directions on the prescription?

When you use your card

When you use your Empire Plan Benefit Card at a network pharmacy or a mail service pharmacy or the designated specialty pharmacy and the pharmacist enters the information into the computer, the computer system will review your recent Empire Plan Prescription Drug Program medication history. If a possible problem is found, a warning message will be flashed to your pharmacist.

The pharmacist may talk with you and your doctor. Once any issues are resolved, the appropriate medication can be dispensed.

Safety review

In addition, a "behind the scenes" safety review is conducted to identify any potential drug therapy-related problems. If a potential problem is detected, the information is reviewed by a clinical pharmacist who notifies your doctor of the possible risks. If two prescribing doctors are involved, both will be notified of the potential problem.

If, as the result of DUR, it is determined that a member may be using prescription drugs in a harmful or abusive manner or with harmful frequency, the Plan reserves the right to limit an enrollee to the use of a single network pharmacy, plus the mail service pharmacy or the designated specialty pharmacy. This process helps your doctor make more informed decisions about your prescription drugs.

Refill too soon

A key component of the DUR safety process implemented for this Program is the application of the "refill too soon" (RTS) edit for all claims submitted under the Program. The RTS Program ensures that the Empire Plan Prescription Drug Program provides safety and utilization review across all supply chains, network pharmacy claims, mail service pharmacy or the designated specialty pharmacy claims and non-network pharmacy claims processed for an individual enrollee. Upon processing of an incoming claim, the previous 180 days of an enrollee's prescription drug claim history are reviewed by the systematic RTS criteria. The RTS edit will cause the claim to reject if the enrollee has consumed (based on days' supply) less than 75 percent of their medication on a cumulative basis over the past 180 days. When a claim is rejected, the pharmacist is sent a message indicating the next refill date for the enrollee. Certain drugs that have quantity-level limits, such as erectile dysfunction drugs, have more restrictive RTS limits to comply with the quantity allowed per days' supply. See *Supply and coverage limits*, page 111, for additional information. The RTS will also take into account the cumulative days' supply on hand.

Confidential service

Confidentiality is key. You can be assured that these reviews are confidential and that pertinent information is shared only with your pharmacist and doctor or as permitted or required by law.

Education Is the Right Prescription

It is important that you understand the drugs being prescribed for you, what they will do and how they should be taken. To help you with that understanding, the Empire Plan Prescription Drug Program has a patient education program.

Additionally, to help your doctor keep up to date on the most current information on prescription drugs, The Empire Plan has a doctor education program.

PRESS 4 OR SAY 4 Prescription Drug Program *Administered by CVS/caremark*

Choose this option for prescription drug benefits and claims, Empire Plan Formulary and the mail service pharmacy.

Representatives are available 24 hours a day, seven days a week.

TTY: 711

General correspondence, prior authorization, grievances

CVS/caremark
Customer Care Correspondence
P.O. Box 6590
Lee's Summit, MO 64064-6590

Mail service pharmacy

CVS/caremark
P.O. Box 2110
Pittsburgh, PA 15230-2110

Claims

Mail completed claim forms to:
The Empire Plan Prescription Drug Program
CVS/caremark
P.O. Box 52136
Phoenix, AZ 85072-2136

Medical exception requests for drugs excluded from the Flexible Formulary

Tell your physician to fax these requests to: 1-888-487-9257

Written appeals

Prescription Claim Appeals
MC 109
P.O. Box 52084
Phoenix, AZ 85072-2084

External appeals

New York State Department of Financial Services
1-800-400-8882

PRESS OR SAY 4 Empire Plan Medicare Rx Program: *Administered by CVS/caremark (SilverScript)*

Choose this option for prescription drug benefits and claims, Empire Plan Formulary and the mail service pharmacy.

Representatives are available 24 hours a day, seven days a week.

TTY: 711

Claims, general correspondence, prior authorization, grievances

SilverScript Insurance Company
P.O. Box 52067
Phoenix, AZ 85072-2067

Mail service pharmacy

CVS/caremark
P.O. Box 2110
Pittsburgh, PA 15230-2110

Medical exception requests for drugs excluded from the Flexible Formulary

Tell your physician to fax these requests to: 1-888-487-9257

Written appeals

Silverscript Insurance Company
Prescription Drug Plans
Coverage Decisions and Appeals Department
P.O. Box 52000
MC 109
Phoenix, AZ 85072-2000

External appeals

New York State Department of Financial Services
1-800-400-8882

If you are unable to resolve a problem with an Empire Plan Program administrator

Contact The Consumer Assistance Unit of the New York State Department of Financial Services at:

New York State Department of Financial Services
One Commerce Plaza, Albany, NY 12257
1-800-342-3736 Monday through Friday, 9 a.m. to 5 p.m. Eastern Time

NYSHIP HMOs

NYSHIP HMO contact information, including phone numbers, TTY numbers, addresses and websites are available in the *Choices* booklet and on the New York State Department of Civil Service website at www.cs.ny.gov.