

Prior Authorization Required From Gainwell Technologies

There are nine situations where prior authorization must be requested from Gainwell Technologies.

Brand Medically Necessary

Prescriptions written as "Brand Medically Necessary" for drugs with A-rated therapeutically equivalent generics require Prior Authorization.

Providers seeking Brand Medically Necessary PA are required to submit a completed federal MedWatch form (FDA 3500) along with the Pharmacy PA form for instances where the patient has a reported allergic reaction to the generic product.

Prior Authorization for Brand Medically Necessary will be granted in cases where documentation indicates the following:

- ***Allergic reaction to excipients (inactive ingredients) in the generic products, FDA 3500 MedWatch form filed***

Adequate generic trial is defined as at least one prescription for the generic product in the past 36 months.

- ***A therapeutic failure to the generic product***

A history of documented previous purchases will be reviewed to determine dosing and compliance issues. Examples of approved documentation of therapeutic failure include adequate time for generic trials (greater > 24 hours use of at least one generic product, unless it is documented that the 1-day trial will be life-threatening), trial on multiple generic manufacturers' products, and the therapeutic failure cannot be attributed to inadequate dosing.

DSS reserves the right to deny or approve on a case-by-case basis depending upon extenuating circumstances. For example, if no other prescribers in the state have reported problems with a certain generic drug and every patient of the prescriber requesting PA is reporting problems, then the problem may not be a failure of the generic product.

Patient requests for brand name drugs will not be accepted for review.

Early Refills

- Early Refill is defined as any prescription in which less than 85% of the medication should have been utilized at the time the prescription is submitted for refill. Unless the drug is a controlled substance, the pharmacist may call Gainwell Technologies to request authorization. The prescriber must call and provide documentation on the PA form for controlled substances. For lost or stolen medications, the prescriber must fax a loss/theft report along with the Prior Authorization form and prescription.

Prior Authorization for Early Refill will be granted in cases where documentation indicates the following.

- ***Change in Direction***

Prior Authorization will be granted if there has been a change in the directions of the medication that substantiates the over-utilization of the prescription. The new prescription must demonstrate the increase in dosing with a change in the number of units per day supply ratio.

- ***Vacation Supply***

Prior Authorization will be granted to a client for a specific medication only once every six months and only a quantity equal to one refill will be authorized.

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• ***Loss/Stolen/Destroyed Medication***

Appropriate documentation of lost/stolen medication includes:

- Insurance report
- Police report
- Letter from pharmacy or prescriber on formal practice site letterhead explaining the circumstances of loss
- Record of admittance to institutional facility, such as a hospital
- Record of arrest or incarceration

Appropriate documentation of destroyed medication includes:

- Insurance report
- Police or fire marshal's report
- Letter from pharmacy or prescriber on formal practice site letterhead explaining the circumstances of loss
- Record of admittance to a long-term care facility
- Record of an institutional facility destruction of a medication in the presence of a witness

Exceptions for documentation can be made in the case of natural disaster, such as flood, hurricane or tornado.

Non-Preferred Medication

New prescriptions for a Non-Preferred medication will require Prior Authorization. Prescribers may switch the recipient to a preferred product to avoid point of sale (POS) issues at the pharmacy, or must submit a Prior Authorization request via fax or mail.

Prior Authorization for Non-Preferred medications will be granted in cases where documentation indicates the following.

- ***Intolerance to Preferred Drugs*** – symptoms of intolerance must be noted on the PA form
- ***Adverse reaction to Preferred Drugs*** – symptoms of intolerance must be noted on the PA form
- ***Inadequate response to Preferred Drugs***
- ***Absence of appropriate formulation with Preferred Drugs***
- ***Deemed medically necessary or medically appropriate***

In situations where both a Non-PDL request also requires a BMN override, the prescriber can request a prior authorization for both situations on the same form.

Optimal Dosage

New prescriptions for medications which exceed the Optimal Dosage will require Prior Authorization. Prescribers may switch the recipient to the preferred dosage of the product to avoid point of sale (POS) issues at the pharmacy, or must submit a Prior Authorization request via fax or mail.

Prior Authorization for Optimal Dosage medications will be granted in cases where documentation indicates the following.

- ***Therapeutic Failure to once daily dosing***
- ***Deemed medically necessary or medically appropriate***

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Hepatitis C Prior Authorization

New prescriptions for Hepatitis C curative agents will require prior authorization. The Hepatitis C PA Form must be filled out by the prescriber, and faxed to Gainwell Technologies for processing. Prior Authorization will be granted in situations where the prescriber indicates:

- Patient is over 18 years of age
- Patient has a diagnosis of Chronic Hepatitis C infection of any genotype 1 through 6 confirmed by HCV ribonucleic acid (RNA) level
- Patient has no evidence of known malignancy of any organ diagnosis in the last 12 months and does not plan to receive or is not currently receiving chemotherapy or radiation therapy
- Patient has no evidence of a terminal disease with life expectancy fewer than 12 months
- Patient is not currently enrolled in hospice

For patients requiring greater than 12 weeks of therapy, the prescriber must document the patient's specific genotypes and rationale for extended therapy. Prescriptions for these agents will be limited to a 14 days' supply per dispensing, once prior authorization has been approved.

Opioid (Long and Short Acting) Prior Authorization

New prescriptions for Long Acting Opioid (LAO) and Short Acting Opioid (SAO) medication will require prior authorization. The Opioid Prior Authorization Form must be filled out by the prescriber, and faxed to Gainwell Technologies for processing or submitted via the prescriber's Secure Web Portal account on the www.ctdssmap.com Web site. Prior Authorization will be granted in situations where the prescriber indicates:

- The patient is age 12 or older;
- The patient has a diagnosis of cancer and/or sickle cell disease;
- The patient is under the care of an Oncologist or Pain Specialist experienced in the use of Schedule II opioids to treat cancer pain;
- The patient does not have any of the following contraindications:
 - Hypersensitivity to opiates,
 - Hypoxia/Hypercarbia,
 - Severe asthma or Chronic Obstructive Pulmonary Disease (COPD), or
 - Paralytic Ileus
- The patient needs an ongoing, continuous course of therapy and not on an as needed basis.

In instances where the individual does not meet all five (5) criteria, the prescriber may write a letter of medical necessity to the Department's Medical Director for consideration. Letters of medical necessity should be faxed alongside the Long Acting Sustained Release Opioid PA Form to (860) 424-4822.

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Cystic Fibrosis Prior Authorization

New prescriptions for the Cystic Fibrosis drugs Kalydeco, Orkambi and Symdeko will require prior authorization.

Prescribers should complete the Cystic Fibrosis Prior Authorization form and fax to Gainwell Technologies for processing. Prior Authorization will be granted in situations where the prescriber indicates:

- Kalydeco:
 - Patient is 2 years of age or older; and,
 - Patient has a diagnosis of cystic fibrosis with one mutation in the CFTR gene that is responsive to ivacaftor based on clinical and/or in vitro assay data
- Orkambi:
 - Patient is 6 years of age or older; and,
 - Patient has a diagnosis of cystic fibrosis homozygous for the F508del mutation in the CFTR gene confirmed by an FDA-cleared CF mutation test
- Symdeko:
 - Patient is 12 years of age or older; and,
 - Patient has a diagnosis of cystic fibrosis homozygous for the F508del mutation in the CFTR gene confirmed by an FDA-cleared CF mutation test

In instances where the individual does not meet both criteria, the prescriber may write a letter of medical necessity to the Department's Medical Director for consideration.

Proprotein Convertase Subtilisin Kexin type 9 (PCSK9) inhibitors Prior Authorization

PCSK9 inhibitors are approved for use in addition to diet and maximally-tolerated statin therapy in adult patients with Heterozygous Familial Hypercholesterolemia (HeFH), or Homozygous Familial Hypercholesterolemia (HoFH), or clinical Atherosclerotic Cardiovascular Disease (ASCVD), such as heart attacks or strokes, who require additional lowering of LDL cholesterol.

New prescriptions for PCSK9 inhibitors will require prior authorization. The PCSK9i Prior Authorization (PA) Form must be filled out by the prescriber, and faxed to Gainwell Technologies for processing. Prior Authorization will be granted in situations where the prescriber indicates:

- The patient is age 18 or older;
- The patient has a diagnosis of atherosclerotic cardiovascular disease (ASCVD), heterozygous familial hypercholesterolemia (HeFH), or homozygous familial hypercholesterolemia (HoFH); and,
- The patient has previously been treated with the highest available dose or maximally-tolerated dose of high intensity statin (atorvastatin or rosuvastatin) AND ezetimibe for at least three continuous months with failure to reach target LDL-C (70 mg/dl for patients with clinical ASCVD and 100 mg/dl for patients with HeFH or HoFH and no history of clinical ASCVD)

In instances where the individual does not meet all three (3) criteria, the prescriber must document any other information relating to the medical necessity.

Step Therapy Prior Authorization

New prescriptions for Non-Preferred drugs in the following classes: Proton Pump Inhibitors (PPIs), Antimigraine Triptans, Acne Agents, Statins (HMG CoA-Reductase inhibitors), and Cytokine and CAM Antagonists will require Step Therapy Prior Authorization.

Prescribers may switch the recipient to a preferred agent to avoid point of sale (POS) issues at the pharmacy, or must submit a Step Therapy Prior Authorization request via fax or mail.

The Step Therapy PA form requires prescribers to explain why the client cannot be treated with one of the currently preferred agents. The prescriber must indicate a contraindication to the preferred agents, or list which preferred product has been utilized in the past, select a reason for the failure, and supply a specific written clinical explanation of the failure.

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Prior Authorization for drugs subject to Step Therapy will be granted in cases where documentation indicates the following:

- *Use of the formulary alternative is contraindicated (e.g. due to hypersensitivity)*
- *The patient has experienced significant adverse effects from the formulary alternative, FDA 3500 MedWatch form filed*
- *Use of the formulary alternative has resulted in therapeutic failure after the course of treatment*
- *Pediatric patient (the patient is younger than 12 years of age)*