

Medicare Part D Exception Review Process for Non-Formulary Drugs



Overview

Pursuant to Section 13 of Public Act 06-188, the Department of Social Services has implemented a new Exception Review process for clients enrolled in a Medicare Part D Prescription Drug Plan (PDP) and the Connecticut Medical Assistance Program [Medicaid, Connecticut Pharmaceutical Assistance Contract for the Elderly and the Disabled Program (ConnPACE) and the Connecticut AIDS Drug Assistance Program (CADAP)] and who are prescribed a medication that is deemed non-formulary by their respective Medicare PDP.

Currently the Department allows the pharmacy provider to submit claims to the Department for payment when the PDP has indicated that a drug is a non-formulary drug. We do not require the pharmacy and/or prescriber to initiate either a potential change to a formulary drug or request an exception from the PDP.

Effective January 1, 2007, the Department has begun assisting the prescribers in choosing a formulary product or pursuing the exception process with the PDP if a change to a formulary medication is not deemed appropriate by the prescriber. The goal is to educate prescribers on the formulary options available to them within each of the Medicare PDP's.

It is important to note that medically necessary non-formulary drugs will continue to be covered regardless of the Medicare Part D Plan's decision to grant or deny an exception. The process we have established will be seamless to the beneficiary. The only time they should receive communication from the Department

is when their prescriber opts to switch them to a PDP formulary drug. When this occurs, the Department will provide the beneficiary a formal notice.

Summary of Pharmacist Procedures

To support this process the Department has also started implementing new claims processing edits and Departmental procedures.

Edit A

Edit A will be set to deny with a new message stating that the Department will pay for a one time fill of this non-formulary drug. This claim will then need to be resubmitted to EDS for the provider to receive payment for this one time fill. Edit A will be set at a state determined dollar threshold.

Edit B

Edit B will be set to post and pay with a new message stating that this is a non-formulary drug that is below the state determined dollar threshold. In this case, the pharmacy should contact the prescriber to determine if changing to a formulary drug is possible or if the prescriber is willing to pursue an exception with the Medicare PDP.

Edit C

Edit C will prevent payment of a non-formulary drug after the first fill has been granted. The pharmacy will receive a message stating: "One time exception fill has been previously used; either the prescriber has agreed to change to a formulary drug, or the PDP has granted an exception for the non-formulary drug". In either case the PDP should be billed as the primary insurer. The purpose of this edit is to prevent paying for more than the one time exception fill after either of the above conditions in this edit have been met.

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New Procedures to Support the Exception Review Process:

Note: These procedures will only apply to the scenario described for Edit A, where the claim initially denies and the claim dollar value exceeds the determined threshold.

The Department's Pharmacy Technicians, upon receiving information on these approved one time fills, will contact the prescriber via phone to discuss the PDP's available formulary options and fax a form with a list of these options. If, after reviewing the list of formulary drugs available, the prescriber decides one is appropriate, he/she will select the suitable formulary medication on the faxed form and return it to the Department. The Department will then enter the prescriber's decision in the DSS exception process database and inform the client via a letter that the prescriber has approved a change to a formulary drug. When the client goes to the pharmacy to pick up the next prescription, he/she should expect that the prescriber has already forwarded a new prescription for the formulary drug.

If the prescriber indicates to the Department that the non-formulary drug should not be substituted with a formulary alternative, the Pharmacy Technicians at the Department will complete the appropriate paperwork on behalf of the prescriber and fax it to him/her for signature. The prescriber will then fax the signed form back to the Department. The Technicians will take this information and begin the exception request process with the PDP. If the exception is approved, the client should receive confirmation from the PDP that the exception request for the non-formulary drug was granted. The pharmacy will, upon resubmission for the second fill to the PDP, receive a paid response and will not have to submit to the Department through the COB-Reject process. The

Department will still cover any remaining co-pay or ingredient cost if the client is in the donut hole. This additional payment would continue to be billed through the co-pay only processing transaction.

Summary of Prescriber Procedures

The prescriber will be contacted by the Department's Pharmacy Technicians to discuss Part D formulary options when a client is prescribed a medication that is deemed non-formulary by their respective Medicare PDP. The prescriber can choose to either: A) change to a formulary drug or B) have the client continue on the non-formulary drug.

If the decision is:

A) To change to a formulary drug, the prescriber should select the appropriate drug from the faxed list, send a new prescription to the client's pharmacy and fax the form back to the Department. It is very important that these steps be followed to ensure that when the client returns to the pharmacy for their next refill of the prescription, the new prescription has already been sent to the pharmacy and is ready to be filled. The Department will, upon receiving back the fax from the prescriber, notify the client in writing of the prescriber's decision to change to a formulary drug.

B) To continue on the non-formulary drug, a Part D exception request form will be completed by the Department's Technicians on behalf of the prescriber and will be faxed to the prescriber for signature. The prescriber will sign and then fax it back to the Department. The Department will then begin the exception request process with the PDP. If the exception is granted, the PDP will now cover the non-formulary drug and determine the client's cost share (co-pay). If the PDP denies the exception request, the Department will initiate the Appeal

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process on the client's behalf. If the Appeal is approved, the non-formulary drug will then be covered by the PDP. If the Appeal is denied, the Department will continue to pay for the non-formulary drug.

Again, It is important to note that the Department will still continue coverage of the non-formulary drug throughout both the exception request and Appeal process.

Potential for Substantial Savings

The Non-Formulary Exception Process, even though in the early stages of implementation, has already evidenced the potential for substantial savings to the State. While the effort has been underway for little over 9 months, the department has already identified savings that should amount to over \$13.5 million annually. Additional information is included below:

- *The Non-formulary Exception Review process began on January 17th with the Pharmacy Technicians reviewing any claims designated as non-formulary costing over \$600.*
- *This dollar threshold was adjusted to over \$400 on February 2nd. This represents 5% of the non-formulary prescriptions and 29% of non-formulary dollars.*
- *The threshold was lowered to \$300 on May 18th. The threshold will be lowered again in September to \$250.*
- *Since the start of the process, we've received 2,401 claims that auto-generated PA's in our system prompting us to take action.*
- *Pharmacy unit staff immediately resolved 502 claims due to claim reversals, inappropriate quantity billings and claims closed due to treatment being discontinued by the prescriber.*

- *Having access to point-of-sale (POS) claims data is extremely beneficial to our staff for this process. It allows the staff to immediately check to see if the pharmacy is billing a claim correctly, is appropriately reversing/rebilling a claim, etc.*
- *682 Exceptions have been approved by the PDP's saving a significant amount of money already. E.g. 1 claim was originally billed to the Department for \$2,709 and after the exception was submitted and approved by the PDP, that amount was reversed and the state was only billed \$5.35.*
- *So far, 645 medications have been changed by the prescriber to one of the Part D plan formulary options. At this point, we are concentrating on high dollar amount drugs and they are not easily substituted. As we continue to lower the dollar threshold, we should see more claims that are easily substitutable.*
- *One prescription alone was being billed and paid for by Medicaid at a cost of \$9,196 per month - we received an exception approval from the PDP. Annualized savings for this one claim totals 110,356.*
- *We have had 164 claims that we have been unable to get approved or changed and the Department continues to pay for. This may be due to various reasons, e.g., inability to reach the prescriber, prescriber not cooperating with the process, Part D plan will not approve the exception, prescriber declines change to formulary medications, etc.*
- *All other exception requests (405) are in process. The pharmacy unit staff follows up after a maximum of 1 week with the prescriber and/or PDP.*
- *Our pharmacy technician's thorough knowledge of medication names and dosages is making this process work smoothly.*
- *The pharmacy unit has had positive feedback from physician staff. They are very receptive to the process since it saves the state money and helps them with their workload.*

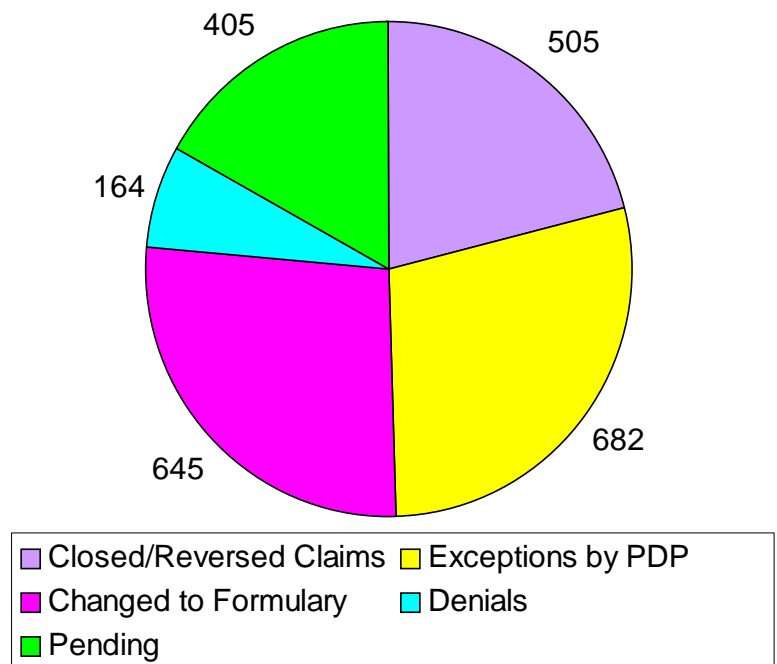
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- Individual contacts have been made with each plan.
- For any plan that has 'plan specific' forms, we have obtained copies of all of those forms and are using them – everything around this process has been specifically tailored to the policies/requirements of the plan.
- Information is being tracked in an Access database.
- EDS is currently in the process of developing monthly cost savings reports.
- Top Non-formulary medications submitted to the Department for Payment are:

Abilify	Aciphex	Actos
Copaxone	Enbrel	Forteo
Gleevec	Humira	Invega
Lamictal	Lipitor	Nexium
Prevacid	Provigil	Renagil
Risperdal	Sensipar	Zyprexa

- Pharmacy Technicians have a dedicated fax and telephone/800 line as follows:
(toll free) 1-866-340-0715;
(local) 860-424-4880; and
(fax) 860-424-4822.
- It is too early in the process to determine whether we have a pattern amongst PDPs, prescribers or medications. As the process evolves, we will be able to easily identify such outliers. A communication has been sent to each of the PDPs alerting them to this process and asking for their full cooperation.

Outcomes of 1888 Reviewed Claims



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