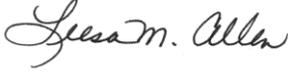




ISSUE DATE August 20, 2015	EFFECTIVE DATE September 28, 2015	NUMBER 99-15-08
SUBJECT Specialty Pharmacy Drug Program – Pharmacy Services		BY  Leesa M. Allen, Deputy Secretary Office of Medical Assistance Programs

IMPORTANT REMINDER: On **October 1, 2015**, the ICD-9 code sets used to report medical diagnoses and inpatient procedures will be replaced by ICD-10 code sets. Additional information is available on the Department of Human Services website at:
http://www.dhs.state.pa.us/provider/icd10information/P_012571

IMPORTANT REMINDER: All providers (including all associated service locations - 13 digits) who enrolled on or before **March 25, 2011** must revalidate their enrollment information no later than **March 24, 2016**. New enrollment application including all revalidation requirements may be found at http://www.dhs.state.pa.us/provider/promise/enrollmentinformation/S_001994. Please send in your application(s) as soon as possible.

PURPOSE:

The purpose of this Bulletin is to:

1. Inform providers that the Department of Human Services (Department) is expanding the Fee-For-Service (FFS) Specialty Pharmacy Drug Program statewide.
2. Issue instructions for providers on how to access drugs under the Specialty Pharmacy Drug Program.

SCOPE:

This Bulletin applies to all licensed pharmacies and prescribing providers enrolled in the Medical Assistance (MA) Program who prescribe or dispense medications to MA recipients whose pharmacy services are covered under the FFS Program.

BACKGROUND:

Federal law permits States to request approval from the Centers for Medicare and Medicaid Services (CMS) to waive specific provisions of the Social Security Act. The Department sought and received approval from CMS to expand the Specialty

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll free number for your provider type

Visit the Office of Medical Assistance Programs Web site at
<http://www.dhs.state.pa.us/provider/healthcaremedicalassistance/index.htm>

Pharmacy Drug Program statewide and require all MA recipients whose pharmacy services are covered under the FFS program to obtain their specialty pharmacy medications from providers designated as preferred specialty providers. The Department issued a Request for Proposals (RFP) and selectively contracted with two specialty pharmacies to provide specialty medications.

DISCUSSION:

The Department's objectives for the Specialty Pharmacy Drug Program are as follows:

- To provide a reliable and convenient dispensing and delivery system for providers and MA recipients that facilitates care.
- To provide a clinical support system designed to optimize therapy management, care coordination, and patient compliance.
- To provide cost-effective services through an accountable Specialty Pharmacy Drug Program.

Specialty Pharmacy Drug Program Preferred Providers

The Department selected the following nationally accredited specialty pharmacy providers through the competitive bidding process to serve as the Department's preferred providers of specialty medications:

Walgreen's Specialty Pharmacy
Telephone: 1-877-220-6194
FAX: 1-877-231-8302

Diplomat Specialty Pharmacy
Telephone: 1-844-891-3332
FAX: 1-855-423-8303

Scope of Drugs Covered Under the Specialty Pharmacy Drug Program

All medications listed in Attachment 1 will be covered under the Specialty Pharmacy Drug Program. Effective September 28, 2015, the Department will limit payment for the medications listed in Attachment 1 to the Department's preferred specialty providers. The Department will not make payment to other enrolled pharmacies and dispensing providers for these medications. However, the Department will continue to make payment to dispensing providers for the administration of these specialty medications.

The Department will periodically update the list of medications covered under the Specialty Pharmacy Drug Program and will notify all providers of any changes to the list of covered medications in advance of any changes.

NOTE: The restriction on payment to the Department's preferred specialty providers applies only to the medications designated by the Department as drugs

covered under the Specialty Pharmacy Drug Program. MA recipients maintain their freedom to choose to get all other non-specialty medications from any provider enrolled in the MA Program and licensed to dispense medications that are willing to serve them. This includes pharmacies and dispensing providers.

MA Program Recipient Coverage and Exemptions

The Specialty Pharmacy Drug Program applies to all MA Program recipients whose pharmacy services are covered under the FFS program. MA recipients who are prescribed a specialty medication covered under the Specialty Pharmacy Drug Program must get that drug from one of the Department's preferred specialty providers.

Exemptions - The Specialty Pharmacy Drug Program does not apply to MA recipients who:

1. Are enrolled in a MA physical health managed care organization (MCO); or
2. Have a third party resource that provides primary coverage of their pharmacy services. Examples include but are not limited to private health insurance and Medicare.

If the MA recipient's other public or private third party coverage does not provide coverage of a medically necessary specialty medication and the MA Program is the primary source of payment, the MA recipient will be required to secure that drug from one of the Department's preferred specialty providers.

MA Program Pharmacy Regulations and Requirements

All regulations in Title 55 Chapters 1101, 1121, and 1150 related to pharmacy services continue to apply to specialty pharmacy medications with the following exceptions:

1. The payment methodology in Chapter 1121 will not apply; fees are negotiated under selective contracting.
2. The requirement for co-payments in Chapter 1101 will not apply; all specialty pharmacy medications dispensed by the specialty pharmacy preferred providers are exempt from co-payments.
3. The requirements related to the Restricted Recipient Program in Chapter 1101 will not apply to the scope of drugs covered under the Specialty Pharmacy Drug Program; MA recipients in the Restricted Recipient Program must get their specialty medications from one of the Department's preferred

providers. MA recipients in the Restricted Recipient Program must continue to get all other non-specialty medications from their restricted providers.

In addition, all operational provisions and utilization management controls related to the coverage of and payment for pharmacy services continue to apply. This includes drugs subject to the Preferred Drug List (PDL), requirements for prior authorization and the guidelines to determine medical necessity, and quantity limits. For example, if a specialty pharmacy drug requires prior authorization, the prescribing provider must still request prior authorization in accordance with the procedures in the Prior Authorization of Pharmacy Services Handbook. The procedures for prescribers to request prior authorization of non-preferred drugs, preferred drugs that require prior authorization, and drugs not subject to the PDL that require prior authorization are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook and on the Department's website at the following link:

<http://www.dhs.state.pa.us/provider/doingbusinesswithdhs/pharmacyservices/pharmacy/priorauthorizationgeneralrequirements/index.htm>.

The following is the link to the MA Program Fee-For-Service Covered Drugs: <http://www.dhs.state.pa.us/provider/doingbusinesswithdhs/pharmacyservices/covereddrugs/index.htm>. Providers can access this file to search for covered drugs and identify whether the drug is subject to the PDL, requires prior authorization, must be obtained through the preferred specialty pharmacies, and has quantity limits. The site also provides a link to the guidelines to determine medical necessity of drugs and classes of drugs that require prior authorization.

The FFS Preferred Drug List (PDL) is available at: www.providersynergies.com/services/documents/PAM_PDL.pdf

The FFS Quantity Limit List is available at: http://www.dhs.state.pa.us/cs/groups/webcontent/documents/document/s_002077.pdf

PROCEDURE:

The following describes the procedures for prescribers and providers to access specialty medications, based upon the site of administration (i.e., prescriber's office, recipient's home, etc.) of the specialty medication.

Dispensing and Delivery Services for Specialty Drugs and Refills Administered in a Provider's Office

1. The prescribing provider can call, fax, or electronically transmit the prescription for a specialty medication to the MA recipient's preferred specialty pharmacy provider at

<p>the contact numbers listed above. NOTE: If the specialty medication requires prior authorization, the prescribing provider must initiate the request for prior authorization before contacting the specialty pharmacy. The procedures to submit a request for prior authorization are located at : http://www.dhs.state.pa.us/provider/doingbusinesswithdhs/pharmacyservices/pharmacypriorauthorizationgeneralrequirements/index.htm</p>
<p>2. The specialty pharmacy provider will ask the prescribing provider to identify where, when, and how often the prescription should be delivered.</p>
<p>3. At initiation of therapy (either a new prescription or the first time using the preferred specialty pharmacy provider), the specialty pharmacy provider will contact the prescribing provider and/or the MA recipient to collect patient information. During the call to the MA recipient, the specialty pharmacy provider will inform the patient about the specialty pharmacy provider's patient care coordination services.</p>
<p>4. The specialty pharmacy provider will mail information packets to the MA recipient. Information for the prescribing provider will be included with the specialty pharmacy medication when delivered to the provider.</p>
<p>5. The specialty pharmacy provider will deliver the specialty medication to the prescribing provider's office on the "needs by" date requested by the prescribing provider.</p>
<p>6. The prescribing provider should notify the specialty pharmacy provider of any changes to the original prescription.</p>
<p>7. The specialty pharmacy will contact the prescribing provider to confirm that the patient is still on therapy before delivering a refill and when a new prescription is required. NOTE: The specialty provider will not deliver the specialty drug without this confirmation.</p>

<p>Dispensing and Delivery Services for Specialty Drugs and Refills Administered in a MA Recipient's Home</p>
<p>1. The prescribing provider can call, fax, or electronically transmit the prescription for a specialty medication to the MA recipient's preferred specialty pharmacy provider at the contact numbers listed above. The prescribing provider can also order any ancillary supplies needed for administration in the home and, if required, indicate the in-home health provider that the recipient prefers to administer the specialty medication.</p>
<p>2. If the MA recipient is currently taking a specialty medication that was previously dispensed by another pharmacy, the MA recipient can contact the specialty pharmacy and ask the specialty pharmacy to contact the prescriber for a new prescription, or the prescribing provider may contact the specialty pharmacy provider directly to provide the prescription.</p>
<p>3. At initiation of therapy (either a new prescription or the first time using the specialty pharmacy provider), the specialty pharmacy provider will contact the MA recipient to collect patient information, inform the patient about the specialty pharmacy provider's patient care</p>

<p>coordination services, make arrangements for home delivery of the specialty medication and any required ancillary supplies, and coordinate in-home nursing services if required.</p>
<p>4. If nursing services are needed to administer the specialty medication in the home, the MA recipient can ask the specialty pharmacy provider to coordinate administration with the home health provider that the MA recipient is currently using or a different MA Program enrolled home health provider that the MA recipient chooses.</p> <p>Home health agencies must follow the standard procedures to request prior authorization of their services. The home health agency will be asked to identify the drug to be administered in the home as part of the request for prior authorization of the requested home health services.</p>
<p>5. The specialty pharmacy provider will include information packets for the MA recipient with the specialty medication or in a separate mailing.</p>
<p>6. The specialty pharmacy will contact the MA recipient to confirm that the patient is still on the therapy before delivering a refill or before contacting the prescribing provider when a new prescription is required. NOTE: The specialty provider will not deliver the specialty drug without this confirmation.</p>

Clinical Support System Services

In addition to dispensing and delivery of specialty medications and coordination of nursing services when needed, both of the Department's preferred specialty pharmacy providers offer a clinical support system for MA recipients that includes, but is not limited to, the following services:

1. A toll free call center available 24 hours per day, 7 days per week to respond to MA recipient's questions about his or her medications
2. Personal medication counseling including, but not limited to:
 - a. Identification and management of side effects of medications
 - b. Storing medications properly
3. Directions for therapy administration and management
4. Monitoring adherence
5. Care coordination

Communications and Outreach

For Providers: The Department provided the preferred specialty pharmacy providers with a list of providers currently prescribing drugs designated as specialty medications. The specialty pharmacy providers will be sending a letter of introduction to all of those providers that includes a description of the services the preferred specialty pharmacies provide and their contact information.

For MA Recipients: The Department sent client specific notices to all MA recipients with a recent history of a paid claim for a specialty medication. The client specific notice identifies the medication and explains what the MA recipient has to do to continue to get that drug. The notice instructs the MA recipient to contact the prescribing provider or the preferred specialty pharmacy provider to ensure no interruption in service. A copy of the client notice is included in Attachment 2.

ATTACHMENTS:

Attachment 1 – Specialty Pharmacy Drug Program List of Covered Drugs

Attachment 2 – MA Program Client Notice

**Specialty Pharmacy Drug Program
Effective September 28, 2015**

Injectable Antipsychotics	Abilify Maintena	Cancer (continued)	Trelstar	Hemophilia (continued)	Alprolix	Immune Deficiency (continued)	Gammaked	Osteoporosis	Boniva Syringe				
	Invega Sustenna		trelinoin		Bebulin		Gammaplex		Forteo				
	Risperdal Consta		Tykerb		Benefix		Gammar-P		ibandronate syringe				
	Zyprexa Relprevv		Vantas		Corifact		Gamunex-C		pamidronate				
Blood Cell Deficiency	Aranesp		Chronic Renal Failure		Votrient		Hepatitis B		Eloctate	Inflammatory Conditions	Ganciclovir	Parkinson's	Prolia
	Epogen				Xalkori				Feiba NF		Hizentra		Reclast
	Granix				Xeloda				Helixate FS		Hyqvia		Xgeva
	Leukine				Xtandi				Hemofil M		Octagam		zoledronic acid
	Mircera				Zelboraf				Humate-P		Privigen		Zometa
	Nplate				Zoladex				Kcentra		WinRho SDF		Apokyn
	Procrit	Zolinza		Koate-DVI	Actemra	Pulmonary Hypertension		Adcirca					
	Promacta	Zydelig		Kogenate FS	Benlysta			epoprostenol sodium					
Botulinum Toxins	Botox	Endocrine Disorders	Zykadia	Hepatitis C	Monoclatale-P		Iron Toxicity	Cimzia	Respiratory Conditions	Flolan			
	Dysport		Sandostatin, -LAR		Novoseven RT			Cosentyx		Letairis			
	Myobloc		Sensipar		Obizur			Enbrel		Opsumit			
	Xeomin		Somatuline Depot		Profilnine			Entyvio		Revatio			
Cancer	8-Mop	Enzyme Deficiencies	Cystadane	Hepatitis C	Recombinate		Lipotropics	Humira	RSV Prevention	Tracleer			
	Actimmune		Aldurazyme		Wilate			Kineret		Bethkis			
	Afinitor, -Disperz		Aralast		Xyntha, Solofuse	Orencia		Cayston					
	Bosulif		Cerdelga		adefovir dipivoxil	Otezla		Esbriet					
	capecitabine		Cerezyme		Baraclude	Remicade		Kalydeco					
	Eligard		Elaprase		entecavir	Simponi		Kitabis					
	Emcyt		Elelyso		Epivir-HBV	Stelara		Ofev					
	Erivedge		Fabrazyme		Hepsera	Xeljanz		Orkambi					
	Gleevec		Glassia		Iamivudine HBV	Deferoxamine		Pulmozyme					
	Gleostine		Lumizyme		Tyzeka	Desferal		TOBI					
	Hexalen	Myozyme	Hereditary Angioedema	Kynamro	tobramycin								
	Ibrance	Naglazyme		Macular Degeneration	Praluent	Xolair							
	Iclusig	Prolastin			Eylea	Jetrea	Synagis						
	Inlyta	Vpriv			Lucentis	Lucentis	Buphenyl						
	Intron-A	Zemaira			Macugen	Macugen	Elitek						
	Jakafi	Genotropin			Visudyne	Visudyne	Fuzeon						
	Leukeran	Genotropin MiniQuick			Multiple Sclerosis	Ampyra	Ampyra	Gattex					
	leuprolide acetate	Humatrope				Aubagio	Aubagio	Illaris					
	lomustine	Increlex				Avonex	Avonex	Iluvien					
	Lupron Depot, Ped	Norditropin Flexpro				Betaseron	Betaseron	Krystexxa					
	Lysodren	Norditropin Nordiflex	Copaxone			Copaxone	Makena						
	Matulane	Nutropin AQ	Extavia	Extavia		Ozurdex							
	Mekinist	Omnitrope	Gilenya	Gilenya		Prialt							
	Nexavar	Saizen	HP Acthar Gel	HP Acthar Gel		Qutenza							
	Pomalyst	Serostim	Lemtrada	Lemtrada		Retisert							
	Revlimid	Somavert	Plegridy	Plegridy		sodium phenylbutyrate							
	Sprycel	Tev-Tropin	Rebif	Rebif	Solesta								
	Stivarga	Zomacton	Tecfidera	Tecfidera	Soliris								
	Sutent	Zorbtive	Tysabri	Tysabri	Supprelin LA								
	Sylatron	Advate	Osteoarthritis	Euflexxa	Euflexxa								
	Tafinlar	Alphanate		Gel-One	Gel-One								
	Tarceva	Alphanine SD		Hyalgan	Hyalgan								
	Targretin			Monovisc	Monovisc								
	Tasigna			Orthovisc	Orthovisc								
	Temodar			Supartz	Supartz								
	temozolomide		Synvisc	Synvisc									
	Thalomid		Synvisc-One	Synvisc-One									
	Thyrogen												

Important Information About Your Medical Assistance Benefits

PLEASE READ CAREFULLY

The Pennsylvania Department of Human Services, Medical Assistance (MA) program has new information about how to get specialty drugs. Our records show that you got the specialty drug listed below. If you are still taking a specialty drug, **the following information is important to you because it explains how you can continue to get your specialty drug under the Specialty Pharmacy Drug Program.**

Your Specialty Drug(s)	

Starting on September 28, 2015, your prescription for a specialty drug must be ordered from one of the preferred specialty pharmacies listed below. The MA Program selected these two specialty pharmacies to serve as the MA program's preferred providers because they showed the Department that they can provide specialty drugs and additional services to support you while you are taking a specialty drug. The preferred specialty pharmacies and contact information are as follows:

Diplomat Specialty Pharmacy

Telephone: 1-844-891-3332
Fax: 1-877-231-8302

Walgreens Specialty Pharmacy

Telephone: 1-877-220-6194
Fax: 1-855-423-8303

What You Should Do

If you are currently getting your specialty drug from Walgreens Specialty Pharmacy, and you want to continue using Walgreen's Specialty Pharmacy, you do not need to do anything. However, you do have the option to use Diplomat to get your specialty drug.

If you are currently getting your specialty drug from Accredo, or any pharmacy other than Diplomat or Walgreen's Specialty Pharmacy, and you get your specialty drug as part of your treatment at your doctor's office, at the clinic, or at a treatment center, talk with your doctor. Let your doctor know that your specialty drug must be ordered from a preferred specialty pharmacy and which specialty pharmacy you want to use. If you do not have a preference, your doctor may help you choose. Your doctor can order your specialty drug from the preferred specialty pharmacy and the drug will be delivered to your doctor's office in time for your treatment. You will receive a call from the new specialty pharmacy to obtain information from you about your health, and to explain the available services and how they will work. You may also receive educational information about your drug. Your doctor will also receive information about the program and will know how to help you. If your doctor does not participate in the MA Program he can find information at www.dhs.state.pa.us.

If you are currently getting your specialty drug from Accredo, or any pharmacy other than Diplomat or Walgreen's Specialty Pharmacy, and your specialty drug is administered by you, by a caretaker, or by a nurse in your home and you know which specialty pharmacy you want to use, you can contact the preferred provider at the telephone number listed above to enroll in the program. If you are not sure which preferred specialty pharmacy you want to use, you can call both and ask for information about each preferred provider's program and services. The preferred specialty pharmacy will contact your old pharmacy and arrange for the prescription to be transferred. The preferred specialty pharmacy will contact you to obtain information about your health, and about other drugs that you take. They will develop a care plan with you including what home nursing services you will be using, if needed, and what educational information you need regarding the use or storage of the drug at your home.

Frequently Asked Questions

What kinds of drugs are "specialty drugs"?

- Drugs that may require special packaging or storage or special training and skills to use properly
- Drugs that may need to be given by injection through a vein or under the skin. This program DOES NOT include insulin. Insulin is not a specialty drug.
- Most drugs given by injection, whether they are given in a doctor's office, by a nurse in the patient's home, or by the patient in the patient's home after receiving training on how to give the drug.

Important Information About Your Medical Assistance Benefits

PLEASE READ CAREFULLY

- A complete list of all of the drugs in the program is on the web at <http://www.dhs.state.pa.us/provider/doingbusinesswithdhs/pharmacyservices/thespecialtypharmacydrugprogram/index.htm> or you can call the MA Call Center at 1-800-657-7925 (TDD/TTY 1-866-872-8970).

What will the Preferred Specialty Pharmacies do?

- Contact you to enroll you in the program. They will ask you some questions to learn more about you and to plan for support services, such as home health nurses that you use while taking the specialty drug.
- Deliver your specialty drug to the place where it will be administered. This can be the doctor's office, the clinic, a treatment center, or your home.
- Teach you and your caretaker, if applicable, on how to use your specialty drug if your doctor determines that you or your caretaker can administer the drug in your home.
- Provide training and information about your specialty drug including how to properly handle and store your drug, possible side effects and how to handle side effects, etc.
- Provide a toll-free, patient call center run by the specialty pharmacy that is available 24 hours a day, 7 days a week to answer any medical questions you may have about your specialty drug.

What should I do if I am already using one of the preferred specialty pharmacies to get my drug?

- If you are currently getting your specialty drug from one of the preferred specialty pharmacies, Diplomat or Walgreens Specialty Pharmacy, and you want to continue using that pharmacy, you do not need to do anything. You can continue to use them.

Does this program apply to everyone on Medical Assistance?

- This program only applies to persons who get a specialty drug with the ACCESS card. It does not apply to anyone in managed care.
- This program does not apply to people whose specialty drugs are covered by Medicare Part B or Part D or by a private health plan policy UNLESS those programs/policies do not cover your particular specialty drug and the drug is covered by the Pennsylvania Medical Assistance Program. In that case, this program does apply to you.

What else should I know about the program?

- You will still be able to get all your non-specialty drugs at the pharmacy that you usually use.
- If your specialty drugs have prior authorization requirements your doctor will need to contact the Department's pharmacy call center. Doctors who participate in the MA Program will have information on how to ask for prior authorization. Doctors who do not participate in the MA program can get this information on the web at www.dhs.state.pa.us.
- Co-payments will not apply to specialty drugs.

Right of Appeal

You do not have the right to appeal the requirement to use one of the Department's two preferred specialty pharmacies to get your specialty drug(s). However, if your specialty drug must be approved by the Department before you can get your prescription and the Department does not approve your prescription, you and your prescribing doctor will get a written notice of the decision. You will have the right to appeal that decision. You will have 30 days from the date on the notice to send an appeal. The written notice will explain how to appeal and where to send the appeal. It will also explain that if you are already taking that medicine and you appeal within 10 days of the date on the written notice, you can continue to get your medicine until the appeal is decided.

For More Information

Call the MA call center at 1-800-657-7925 (TDD 1-866-872-8969/TTY 1-866-872-8970), if you have any questions. More information about the Specialty Pharmacy Drug Program is available on the Department's website at: <http://www.dhs.state.pa.us/provider/doingbusinesswithdhs/pharmacyservices/thespecialtypharmacydrugprogram/index.htm>