



VYTL  **NE**
SPECIALTY PHARMACY

Welcome Packet

Your guide to helpful resources, support,
and everything you need to get started.



Welcome!

Dear Patient,

Welcome to VytlOne Specialty Pharmacy. We are pleased to serve you and all of your specialty pharmacy needs.

Si necesita ayuda en español, por favor contacte (866) 629-6779.

If you need assistance in a language other than Spanish, please contact us at the phone number listed on your prescription bottle.

Team members are available Monday to Friday from 7am to 7pm Central time. Our on-call team consists of customer service and clinical representatives. They are available after hours and on weekends for urgent matters.

We look forward to serving you from one of our three specialty pharmacies:

Amarillo, Texas

216 S. Polk St.
Amarillo, TX 79101
Phone: 866-629-6779
Fax: 866-217-8034

Bogart, Georgia

150 Cleveland Rd., Suite B
Bogart, GA 30622
Phone: 800-818-6486
Fax: 800-818-6490

Lubbock, Texas

(Rare and Orphan Disease Center of Excellence)
6101 43rd St., Suite C
Lubbock, TX 79407
Phone: 800-658-6046
Fax: 800-791-7851

VytlOne Specialty Pharmacy of Lubbock and Amarillo provide medication services to all 50 states and offer infusion services within their licensed regional areas. VytlOne Specialty Pharmacy of Bogart provides medication services to 48 states (excluding Kansas and California).

Please note that VytlOne Specialty Pharmacy may use another pharmacy within the VytlOne network to process your order. We look forward to providing you with the best service possible.

If any printed materials are needed, we will gladly provide them. We know you have options, and we thank you for choosing VytlOne Specialty Pharmacy.

Sincerely,

The VytlOne Specialty Pharmacy Team

If you need assistance in another language, please call the phone number listed on your prescription bottle.

Spanish:

Si necesita ayuda en otro idioma, llame al (866) 629-6779.

Chinese (simplified):

如果您需要其他语言的帮助，请致电 (866) 629-6779.

Chinese (traditional):

如需其他語言的協助，請致電：1 (866) 629-6779.

Filipino:

Kung kailangan mo ng tulong sa ibang wika, mangyaring tumawag (866) 629-6779.

Vietnamese:

Nếu bạn cần hỗ trợ bằng ngôn ngữ khác, vui lòng gọi (866) 629-6779.

Arabic:

لاصتال اى جري، ىرخ أة غلب ةدع اسم ىل اى عا حب تنك اذا (866) 629-6779

French:

Si vous avez besoin d'aide dans une autre langue, veuillez appeler (866) 629-6779.

Korean:

다른 언어로 도움이 필요하면 전화해 주세요. (866) 629-6779.

Russian:

Если вам нужна помощь на другом языке, позвоните (866) 629-6779.

Portuguese (Brazilian):

Se precisar de ajuda em outro idioma, ligue para (866) 629-6779.

Haitian Creole:

Si w bezwen asistans nan yon lòt lang, tanpri rele (866) 629-6779.

Hindi:

यदआपको किसी अन्य भाषा में सहायता की आवश्यकता हो तो कृपया कॉल करें (866) 629-6779.

Japanese:

多言語でのサポートが必要な場合は、1 (866) 629-6779 にお電話ください。

Pashto:

که تاسو په بله ژبه کې مرستې ته اړتیا لرئ، مهرباني وکړئ په 1 (866) 629-6779 اړیکه ونیسئ.



What Is Specialty Pharmacy and How Can Specialty Pharmacists Help Me?

Specialty Pharmacy

A specialty pharmacy is different from a retail pharmacy. A specialty pharmacy provides medications for people with chronic, complex, rare, or serious health conditions. The medications often require specific administration and monitoring. Specialty pharmacies also work more closely with patients, striving to improve patients' lives by focusing on adherence, effectiveness, and appropriateness of treatment.



Specialty pharmacists can help me by:

- Giving you details and guidance about the medications you are taking.
- Providing more information about your condition.
- Assisting you in managing your side effects.
- Coordinating prior authorization requests.
- Supporting you with mental health challenges that may arise.
- Finding you additional support.
- Giving you tips to stay healthy.
- Finding you ways to pay for your medication.
- Working with your doctor's office to coordinate care.

Our specialty-trained staff members will work with you to discuss your treatment plan, and we will talk with you about any questions or concerns. We are always here to help you.

What to Expect

Having a chronic disease or serious illness can be hard at times. At VytlOne Specialty Pharmacy, our staff works with you, your doctors and nurses, and your family and caregivers to create one healthcare team.

Refills

You will be contacted by a staff member about one week before your refill date. If you would like to contact us for a refill, you can call us and speak to a patient care coordinator to process your refills. If needed, we will help you with a process to refill a prescription which might be limited by your prescription benefit plan.



Drug Substitutions

From time to time, we have to substitute generic drugs for brand-name drugs. This could happen because your insurance company wants the generic to be used or to lower your copay.



Adverse Effects

If you are having adverse effects from the medication, please reach out to your doctor or pharmacy.



Regular Follow-up

Getting your medicines and medical supplies quickly and smoothly is key. We will be in close contact with you during your treatment and can help you with any problems.



Partnering with Your Doctor

We rely on and help you to maintain open communication with your doctors and caregivers. We are here to make sure any issues you may be having with your treatment are handled right away.



Drug Recalls

If your medication is recalled, the specialty pharmacy will contact you with more information as directed by the FDA or drug manufacturer.

24/7 Support

Our specialty pharmacy staff is available 24 hours a day, 7 days a week. Contact us if you have any questions or concerns about your medicine, think you have a reaction or allergy to your medicine, change your medicine use, change your contact information or delivery address, or change your insurance information or payment type. You can also check the status of your order, discuss an order delay, reschedule your delivery, or get claims-related information.

Prescription Transfers

If our pharmacy can no longer service your medication, a pharmacist will transfer your prescription to another pharmacy. We will let you know about this transfer.

If you feel that our pharmacy can't meet your needs, we can transfer your prescription to the pharmacy of your choice.

Safe Disposal of Sharps

If you use injectable medications, a sharps container is important to safely get rid of needles. Sharps containers may be bought at a local pharmacy or an online retailer. For more information about your state's sharps disposal options, visit www.safeneedledisposal.org, or call 1-800-643-1643 or email info@safeneedledisposal.org

Proper Disposal of Medications that are Not Used

For information on how to properly get rid of unused medications, please contact Vyt!One Specialty Pharmacy or go to the FDA websites listed below for more information and instructions.



FDA: How to Dispose of Unused Medicines

<http://www.fda.gov/forconsumers/consumerupdates/ucm101653.htm>



FDA: What to know about Disposal of Unused Medicines

<http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/ensuringsafeuseofmedicine/safedisposalofmedicines/ucm186187.htm>



Benefits

Treatment can be expensive, and we will help you manage the challenges of the healthcare system by looking at every choice open to you. Our relationship with insurers helps us give you information and answers about your drug and medical benefits. Your quality of care is important to us.



Financial Responsibility and Financial Assistance

Before your care begins, a staff member will tell you about the financial responsibilities you face that are not covered by your insurance or other third-party sources. These include but are not limited to out-of-pocket costs such as deductibles, co-pays, co-insurance, and annual and lifetime co-insurance limits.

We have access to financial assistance programs to help with co-payments to prevent gaps in your therapy. These programs include discount coupons from drug manufacturers, co-payment vouchers, and help from disease management foundations and drug companies.



Insurance Claims

We will send in claims to your health insurance company on the date your prescription is filled. If the claim is rejected, a staff member will let you know so that we can work together to fix the issue. There may be financial obligations if our pharmacy is out of network for your health benefit plan. If that happens, the pharmacy will reach out to you and communicate your options.



Co-payments

We must collect all co-payments before shipping your medication. Co-payments can be paid by credit card, electronic checking account, debit, over the phone, and check or money order through the mail. Visit VytlOneSpecialty.com to make payments.

National Drug Prescription Take Back Day

The Drug Enforcement Administration sponsors drug take back days in April and October every year. Go to dea.gov for information about locations and dates.

Patient Education Resources

Scan the QR code for info on your condition, support resources, and rare disease registries.



www.vytlonespecialty.com

We value your feedback. Please take a moment to fill out our satisfaction survey.

www.yourpharmacycares.com

Complaints



Patients and caregivers have the right to voice complaints and/or recommendations on pharmacy services. Patients and caregivers can do so by phone, fax, writing, or emailing the pharmacy directly or by reaching out to any of the following:

Texas State Board of Pharmacy

Website: <https://www.pharmacy.texas.gov/consumer/complaint.asp>

Telephone: (800) 821-3205 Option 5

Address: 1801 Congress Avenue, Austin, TX 78701

Anyone may file a complaint against a pharmacy, but complaints must be received in writing. A consumer may fill out the online complaint form or call the phone number above to have one mailed to you.

Georgia State Board of Pharmacy

Website: <https://gbp.georgia.gov/about-us/contact-us>

Telephone: (404) 651-8000

Address: 2 Martin Luther King Jr. Dr. SE, 11th Floor - East Tower, Atlanta, GA 30303

To file a complaint against a pharmacy, please contact the Georgia State Board of Pharmacy by phone using the number listed above.

National Association of Boards of Pharmacy (NABP)

Website: <https://nabp.pharmacy/about/boards-of-pharmacy/>

For further information, you may contact the phone number for your state listed on the website.



URAC

Website: <https://www.urac.org/contact/file-a-grievance/>

Telephone: (202) 216-9010

Address: 1220 L Street, NW, Suite 400, Washington, DC 20005

To file a complaint about a URAC-accredited organization, go to the website listed above and fill out the complaint form and submit it.

The Joint Commission

Website: https://www.jointcommission.org/report_a_complaint.aspx

Email Address: patientsafetyreport@jointcommission.org

Fax Number: (404) 651-8000

Address: 1 Renaissance Blvd., Oak Brook Terrace, IL 60181

To file a concern about a healthcare organization, you may submit the concern online, or via email, fax, or regular mail.

ACHC

Website: <https://www.achc.org/contact/>

For further information, you may contact ACHC toll-free at (855) 937-2242 or (919) 785-1214 and request the Complaints Department.

Key Roles in Your Care

The staff at VytlOne Specialty Pharmacy understands that your medical condition is complex and requires special knowledge when working with your medical provider and insurance company.

Our **Patient Management Program** is designed to provide you with the personal service necessary to help you achieve the most benefit from your therapy.

Patient Management Program

- Access to clinically trained personnel 24 hours a day/7 days a week
- Coordination of prior authorization with your insurance company
- Medication compliance monitoring
- Mailing medication to you at no additional charge
- Training, education, and counseling
- Refill reminders
- myVytlOneLink notifications and communication

VytlOne's Patient Management Program enables our specialty pharmacy staff to provide treatment-specific monitoring of your medications and progress. This program can provide assistance managing side effects or understanding your medications. Designed collaboratively by you, your doctor, your nurse, and your pharmacist, the program can help you get the most from your medication every step of the way.

Our clinically-trained staff includes pharmacists, case managers, and patient care coordinators. They are available to assist you throughout your journey.

Remember to save us as a contact in your phone so you don't miss important messages and calls.

The Patient Management Program is provided to you at no additional cost, and your participation is voluntary. You may opt out of the program at any time by contacting one of the pharmacy team members.

Tips for Following Your Treatment Plan

1

Read all the information you receive about your medication. It is important that you understand how your medicine works and how to take it correctly.

2

Have a routine. Take your medicine at the same time every day as directed by your care team.

3

When appropriate, use a pill organizer. Fill it at the start of every week, so your medications are ready to go.

4

Use medication reminders. Texts, a medication calendar, or phone alerts can help you.

5

Keep a medication journal. Tracking your medicine can help you stay organized. Keeping a record can help your care team. You can keep track of any side effects there, too.

6

Use the support provided by VytIOne Specialty Pharmacy. If you are having trouble following your medication plan, we can assist you. Keep communication open with us.

7

Seek support from family and friends. They can help with reminders and offer encouragement.

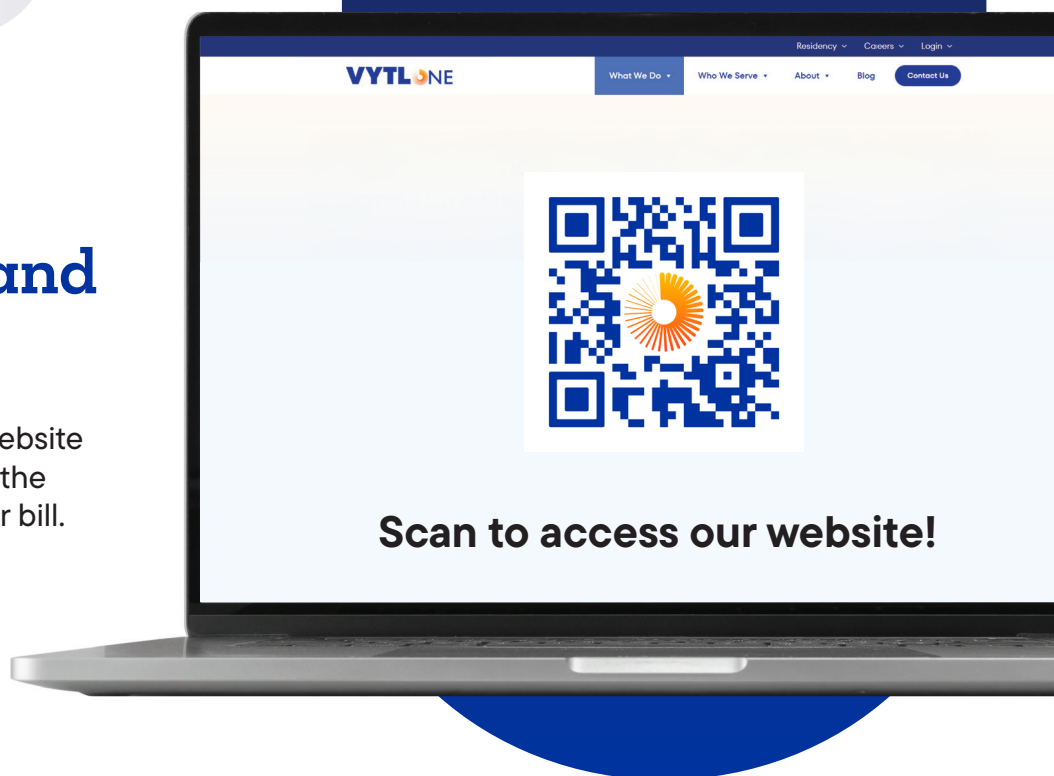
8

Get financial assistance. Specialty medicines can be expensive. We are here to help you access financial assistance programs and other ways to pay for your medicine.



Digital Tools to Stay on Top of Your Condition and Prescriptions

The VytlOne Specialty Pharmacy website includes useful resources, a link to the patient portal, and a link to pay your bill.



What Can You Do on the VytlOne Specialty Pharmacy Website?

1. The “Access my Account” section allows you to access the patient portal and pay your bill.
2. Download forms including authorization and consent forms, referral forms, and infusion-related forms.
3. Patient resources include information on various conditions that may help you as you learn more about your treatment.

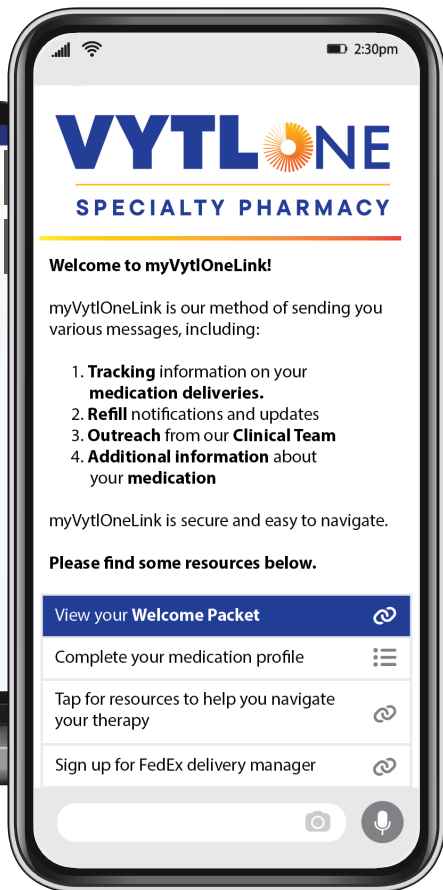
What Can You Do on the Patient Portal?

When you are on the patient portal click on the “Get started today” button and complete your registration. You or your caregiver will need to create a login and password, fill out all the required information, and agree to terms.

After registering, you will be able to log in to your account. On the patient portal, you can:

- | | |
|------------------------------------|--------------------------------------|
| 1. Refill your prescription. | 3. Update your personal information. |
| 2. Check the status of your order. | 4. See your prescription history. |

If you have questions, please call VytlOne Specialty Pharmacy at the number on your prescription label.



How Can I Stay Up to Date on My Prescriptions?

myVytlOneLink

myVytlOneLink is a personalized communication tool for our patients and their caregivers. It helps you receive refill notifications and other useful information to your mobile device.



Stay Connected

VytlOne Specialty Pharmacy can connect with you directly on your mobile device, offering an easy way to make sure you are getting the most value from us.



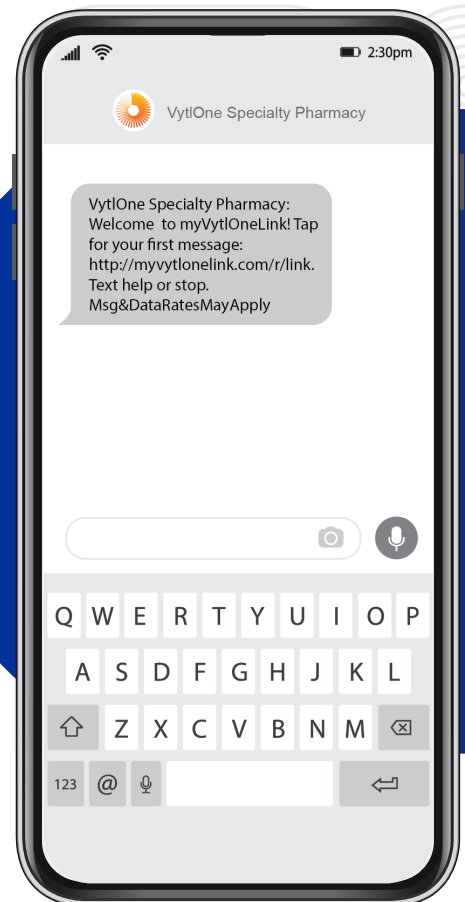
Request Refills

VytlOne Specialty Pharmacy can send you refill reminders using myVytlOneLink. Simply click the link in the text message to quickly refill your prescriptions on your mobile device.



Be Informed

Receive information related to your medication and condition, such as appropriate injection techniques.



How Does It Work?

If you provide your mobile phone number to VytlOne Specialty Pharmacy, you will be auto-enrolled in the myVytlOneLink program. You will receive a welcome message confirming your enrollment. When VytlOne Specialty Pharmacy has a message available for you, you will receive a text message from myVytlOneLink that takes you to your secure, personalized communication channel. You may opt out at any time. Simply text STOP to any myVytlOneLink message you've previously received.



Information for Caregivers

Caregivers play an important role. Although it can be rewarding, we know that caregiving can be labor intensive and difficult at times. We are here to help guide and support you through the process as we work together to care for your loved one.

Upon initial diagnosis, having accurate information about the course of treatment and prognosis is essential. Asking questions and taking notes, particularly at the outset, is key. Don't be afraid to ask healthcare professionals to repeat instructions or elaborate further. You should understand the medication, including the dosage, administration, possible side effects, and potential drug interactions. It can also be useful to observe your loved one and take notes on your observations. If problems arise at any point while caring for your loved one, know who to call and when.

You can be involved in your loved one's care in many ways. You can act as a liaison among your loved one, medical staff, and the pharmacy. Please be sure that the patient has signed the requisite legal documents so that you are free to speak with their care team.

As treatment progresses, your role may change, and you may need to adapt. Always be mindful of the therapeutic goals of treatment and, if you can, assist in tracking whether those goals are being met. With an injectable medicine, your loved one may be reluctant at first to give themselves a shot, but that could change as time goes on. Encourage your loved one to maintain a level of independence consistent with their capabilities, which may change over time.

You may be able to assist with:

- Injecting medicines.
- Making appointments.
- Setting up transportation.
- Picking up medication.
- Monitoring symptoms.
- Noticing side effects.
- Tracking medication compliance.
- Providing moral support.



Assistance with medication compliance and management of side effects will vary based on factors like whether you and your loved one live together or separately. That one difference can determine much of your role. If you are in the same home, you can observe side effects and assist in their management. If you are not in the same home, you can also be helpful by providing reminders and other assistance. A phone call to check in can have a tremendous impact, keeping your loved one engaged with their therapy.

You can also provide support on the mental health front. Having an in-person conversation or even talking over the phone offers the opportunity for active listening. You can also connect your loved one with support groups—support from others in the same situation can be reassuring.

Remember, too, that you need to take care of yourself. If the caregiving is very intensive, rest is especially important. When the caregiving situation starts to feel like a burden, you should step away and remember that your loved one did not ask to be in this situation. Focus on eating healthy foods and getting enough sleep. You need to stay healthy so you can best help your loved one.

If you have questions about caregiving, please reach out to us at (866) 629-6779.

Home Safety Information

Here are some helpful guidelines to help you keep a careful eye on your home and maintain safe habits. The safe way is always the best way to do things. Shortcuts may hurt. Correct unsafe conditions before they cause an accident. Take responsibility. Keep your home safe. Keep emergency phone numbers handy.



Cleaning Your Hands

The most important step to prevent the spread of germs and infections is hand washing. Wash your hands often. Be sure to wash your hands each time you:

- Touch any blood or body fluids.
- Touch bedpans, dressings, or other soiled items.
- Use the bathroom or bedpan.
- Cough, sneeze, or blow your nose.
- Prepare or consume food.

How you should clean your hands with soap and water:

- Wet your hands and wrists with warm water.
- Using soap, work up a good lather, and rub hard for 20 seconds or longer.
- Rinse your hands well.
- Dry your hands well.
- Use a clean paper towel to turn off the water and throw the paper towel away.

How you should clean your hands with alcohol-based hand sanitizers (waterless hand cleaners):

- For gel product, use one application.
- For foam product, use a golf-ball size amount.
- Apply product to the palm of your hand.
- Rub your hands together and cover all surfaces of your hands and fingers until they are dry. This should take around 20 seconds.



Medication

- If children are in the home, store medications and poisons in childproof containers that are out of reach.
- All medication should be labeled clearly and left in original containers.
- Do not give or take medications that were prescribed for other people.
- When taking or giving medication, read the label and measure doses carefully and know the side effects of the medication you are taking.
- Review and understand storage requirements for your medication.



Mobility Items

When using mobility items such as canes, walkers, wheelchairs, or crutches, you should use extra care to prevent slips and falls.

- Use extreme care to avoid using walkers, canes, or crutches on slippery or wet surfaces.
- Always put wheelchairs or seated walkers in the lock position when standing up and before sitting down.
- Wear shoes when using these items and try to avoid obstacles in your path as well as soft and uneven surfaces.



Slips and Falls

Slips and falls are the most common and often the most serious accidents in the home. Here are some things you can do to help prevent them:

- Arrange furniture to avoid an obstacle course.
- Secure throw rugs (removing them is often the safer option).
- Install handrails on all stairs, showers, bathtubs, and toilets.
- Keep stairs clear and well lit.
- Place rubber mats or grids in showers and bathtubs.
- Use bath benches or shower chairs if you have muscle weakness, shortness of breath, or dizziness.
- Wipe up all spilled water, oil, or grease immediately.
- Keep floors clear of electrical cords and other items.
- Keep drawers and cabinets closed.
- Install good lighting to avoid searching in the dark.



Lifting

If it is too big, too heavy, or too awkward to move alone, get help. Here are some things you can do to prevent lower back pain or injury:

- Stand close to the load with your feet apart for good balance.
- Bend your knees and straddle the load.
- Keep your back as straight as possible while you lift and carry the load.
- Avoid twisting your body when carrying a load.
- Plan ahead and clear your path before moving.



Electrical Accidents

Watch for early warning signs like overheating, a burning smell, and sparks. Unplug the appliance and get it checked right away. Here are some things you can do to prevent electrical accidents:

- Keep cords and electrical appliances away from water.
- Do not plug cords under rugs, through doorways, or near heaters. Check cords for damage before use.
- Extension cords must have a big enough wire for larger appliances.
- If you have a broken plug outlet or wire, get it fixed right away.
- Use a ground on three-wire plugs to prevent shock in case of electrical fault.
- Do not overload outlets with too many plugs.
- Use three-prong adapters when necessary.



Gas Leaks

If you smell gas:

- Open windows and doors.
- Shut off appliance involved
- Don't use matches or turn on electrical switches.
- Don't use a telephone until safely away from the affected area.
- Don't light candles.
- Call gas company from a neighbor's home.
- If your gas company offers free annual inspections, take advantage of them.



Fire

If you have a fire or suspect fire:

1. Take immediate action per plan. Escape is your top priority.
2. Get help on the way with no delay. Call 9-1-1.
3. If your fire escape is cut off, close the door and seal the cracks to hold back smoke and signal help from the window.

Do not use the elevator in a fire emergency. You may notify the fire department ahead of time if you have a disability or special needs. Here are some steps to prevent fires:

- Pre-plan and practice your escape.
- Plan for at least two ways out of your home.
- If your fire exit is through a window, make sure it opens easily.
- If you are in an apartment, know where the exit stairs are located.
- Install smoke detectors because they are your best early warning. Test them frequently and change the battery every year.
- If there is oxygen in use, place a “No Smoking” sign in plain view of all people entering the home.
- Throw away old newspapers, magazines, and boxes.
- Empty wastebaskets and trashcans regularly.
- Do not toss matches into wastebaskets unless you know they are out and have been wetted down first.
- Have your chimney and fireplace checked frequently.
 - Look for and repair cracks and loose mortar.
 - Keep paper, wood, and rugs away from area where sparks could hit them.
- Be careful when using space heaters.
- Follow instructions when using heating pad to avoid serious burns.
- Check your furnace and pipes regularly.
 - If nearby walls or ceilings feel hot, add insulation.
- Keep a fire extinguisher in your home and know how to use it.



Emergency and Disaster Preparedness Plan

Vyt!One Specialty Pharmacy has a complete emergency preparedness plan in case a disaster happens.

Disasters could be fire to our facility, chemical spills in the community, snowstorms, hurricanes, tornadoes, and community evacuations. Our main goal is to continue to service your prescription care needs. When there is a threat of disaster or bad weather in the local area where the specialty pharmacy is, Vyt!One Specialty Pharmacy will contact you before any expected problems.

If there is a threat of disaster or bad weather in an area you live in, it is up to you to contact the pharmacy before the occurrence (if possible). This process will ensure you have enough medication to get you through the time period.

Vyt!One Specialty Pharmacy will use every resource we can to continue to service you. However, there may be times where Vyt!One Specialty Pharmacy cannot meet your needs due to the scope of the disaster. In that case, you should use the resources of your local rescue or medical facility.



Please read the guide below to help you in case of an emergency or disaster.

1. The pharmacy will call you 3-5 days before any expected bad weather emergencies.
2. The pharmacy will send your medication by courier or FedEx priority overnight during any bad weather emergencies.
3. If the pharmacy cannot get your medication to you before the bad weather emergency happens, the pharmacy will transfer your medication to a local pharmacy so you do not go without medication.
4. If a local disaster happens and the pharmacy cannot reach you or you cannot reach the pharmacy, please listen to your local news and rescue centers for advice on getting medication. Visit your local hospital right away if you will miss a dose.
5. The pharmacy recommends all patients leave a second emergency phone number.
6. If you have an emergency that is not environmental but personal and you need your medication, please contact the pharmacy when you can and we will help you.

Definitions

Adverse event: any undesirable experience associated with the use of a medical product in a patient

Brand-name drug: a drug that uses a specific name or trademark and is protected by a patent. Brand-name drugs are often more expensive than generic drugs

Care coordination: organization and integration of patient care activities across healthcare settings and providers

Chronic disease management: an integrated approach to managing a chronic illness or condition. Includes monitoring and coordinating treatment

Co-insurance: the amount of money that you pay after meeting your deductible; it is a percentage of the healthcare service you received

Co-payment: also known as copay, a fixed fee that you pay after your deductible has been met. Often associated with a doctor visit or a prescription

Deductible: the amount of money that you need to pay before your insurance policy starts paying for covered expenses

Formulary drug list (also known as a drug list): list of prescription drugs covered by your insurance plan

Drug tiers: coverage levels for drugs; drugs on different levels will have different costs

Generic drug: a drug that contains the same ingredients as a brand name drug; a generic drug usually costs less than the brand name version

Infusion drugs: drugs delivered directly into the bloodstream through a vein

Injectable drugs: medications delivered by needle

Limited distribution drugs (LDDs): drugs to treat rare or complex medical conditions; these drugs are only offered through a select number of pharmacies

Medical supplies: medical items used to treat or diagnose an illness, injury, or condition

Medication compliance (also called adherence): taking medication as intended and prescribed

Medication profile: a list of the medications that you are taking

Out-of-pocket cost: the amount of money you will pay without being reimbursed by your insurance company

Patient assistance program: program that can help patients pay for and get their specialty medications

Prior authorization: approval (authorization) that may be required before you get a prescription filled in order for that prescription to be covered by the insurance company

Sharps: sharp items like needles, syringes, and lancets, which are used to inject medications

Side effect: an unintended effect of a medicine (some examples would be fatigue, excessive thirst, rashes, etc.)

Specialty drugs: medications used to treat rare, complex, or chronic conditions

Specialty pharmacy: pharmacy that provides medications for people with rare, complex, or chronic conditions

Temperature-controlled packaging: a type of packaging that keeps items at a certain temperature during shipment and distribution

Enrollee name: _____(optional)

Drug and prescription number: _____(optional)

Medicare Drug Coverage and Your Rights

You have the right to ask for a coverage determination from your Medicare drug plan to provide or pay for a drug you think should be covered, provided, or continued. You also have the right to ask for a special type of coverage determination called an **“exception”** if you:

- Need a drug that’s not on your plan’s list of covered drugs
- Believe a coverage rule (like prior authorization or a quantity limit) shouldn’t apply to you for medical reasons
- Need to take a non-preferred drug and you want the plan to cover the drug at a preferred drug price

How to ask for a coverage determination

To ask for a coverage determination, you or your prescriber can call your Medicare drug plan’s toll-free phone number on the back of your plan membership card, or go to your plan’s website. You can ask for an expedited (24 hour) decision if your health could be seriously harmed by waiting up to 72 hours for a decision.

Be ready to tell your Medicare drug plan:

- The name of the prescription drug, including dose and strength (if known)
- The name of the pharmacy that tried to fill the prescription
- The date you tried to fill the prescription
- If you ask for an exception, your prescriber will need to explain why you need the off-formulary or non-preferred drug, or why a coverage rule shouldn’t apply to you

Your Medicare drug plan will send you a written decision. If coverage isn’t approved and you disagree with this decision, you have the right to appeal. The plan’s notice will explain why coverage was denied and how to ask for an appeal.

Get help and more information

Look at your plan materials or call 1-800-MEDICARE (1-800-633-4227) for more information about how to ask for a coverage determination. TTY users can call 1-877-486-2048. For help contacting your plan, call 1-800-MEDICARE.

To get this form in an accessible format (like large print, Braille, or audio) contact your Medicare drug plan. You also have the right to file a complaint if you feel you've been discriminated against. Visit [Medicare.gov/about-us/accessibility-nondiscrimination-notice](https://www.medicare.gov/about-us/accessibility-nondiscrimination-notice), or call 1-800-MEDICARE (1-800-633-4227) for more information. TTY users can call 1-877-486-2048.

PRA Disclosure Statement According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0975. This information collection is used to provide notice to enrollees about how to contact their Part D plan to request a coverage determination. The time required to complete this information collection is estimated to average 1 minute per response, including the time to review instructions, search existing data resources, gather the data needed, to review and complete the information collection. This information collection is required under § 423.562(a)(3) and an associated regulatory provision at § 423.128(b)(7)(iii). If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

MEDICARE DMEPOS SUPPLIER STANDARDS

Note: This is an abbreviated version of the supplier standards every Medicare DMEPOS supplier must meet in order to obtain and retain their billing privileges. These standards, in their entirety, are listed in 42 C.F.R. 424.57(c).

1. A supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements.
2. A supplier must provide complete and accurate information on the DMEPOS supplier application. Any changes to this information must be reported to the National Supplier Clearinghouse within 30 days.
3. A supplier must have an authorized individual (whose signature is binding) sign the enrollment application for billing privileges.
4. A supplier must fill orders from its own inventory, or contract with other companies for the purchase of items necessary to fill orders. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or any other Federal procurement or non-procurement programs.
5. A supplier must advise beneficiaries that they may rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental equipment.
6. A supplier must notify beneficiaries of warranty coverage and honor all warranties under applicable State law, and repair or replace free of charge Medicare covered items that are under warranty.
7. A supplier must maintain a physical facility on an appropriate site and must maintain a visible sign with posted hours of operation. The location must be accessible to the public and staffed during posted hours of business. The location must be at least 200 square feet and contain space for storing records.
8. A supplier must permit CMS or its agents to conduct on-site inspections to ascertain the supplier's compliance with these standards.
9. A supplier must maintain a primary business telephone listed under the name of the business in a local directory or a toll free number available through directory assistance. The exclusive use of a beeper, answering machine, answering service or cell phone during posted business hours is prohibited.
10. A supplier must have comprehensive liability insurance in the amount of at least \$300,000 that covers both the supplier's place of business and all customers and employees of the supplier. If the supplier manufactures its own items, this insurance must also cover product liability and completed operations.
11. A supplier is prohibited from direct solicitation to Medicare beneficiaries. For complete details on this prohibition see 42 CFR§424.57 (c) (11).
12. A supplier is responsible for delivery of and must instruct beneficiaries on the use of Medicare covered items, and maintain proof of delivery and beneficiary instruction.
13. A supplier must answer questions and respond to complaints of beneficiaries, and maintain documentation of such contacts.
14. A supplier must maintain and replace at no charge or repair cost either directly, or through a service contract with another company, any Medicare-covered items it has rented to beneficiaries.
15. A supplier must accept returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and rented or sold) from beneficiaries.



16. A supplier must disclose these standards to each beneficiary it supplies a Medicare-covered item.
17. A supplier must disclose any person having ownership, financial, or control interest in the supplier.
18. A supplier must not convey or reassign a supplier number; i.e., the supplier may not sell or allow another entity to use its Medicare billing number.
19. A supplier must have a complaint resolution protocol established to address beneficiary complaints that relate to these standards. A record of these complaints must be maintained at the physical facility.
20. Complaint records must include: the name, address, telephone number and health insurance claim number of the beneficiary, a summary of the complaint, and any actions taken to resolve it.
21. A supplier must agree to furnish CMS any information required by the Medicare statute and regulations.
22. All suppliers must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment for those specific products and services (except for certain exempt pharmaceuticals).
23. All suppliers must notify their accreditation organization when a new DMEPOS location is opened.
24. All supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare.
25. All suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation.
26. A supplier must meet the surety bond requirements specified in 42 CFR § 424.57 (d).
27. A supplier must obtain oxygen from a state-licensed oxygen supplier.
28. A supplier must maintain ordering and referring documentation consistent with provisions found in 42 CFR § 424.516(f).
29. A supplier is prohibited from sharing a practice location with other Medicare providers and suppliers.
30. A supplier must remain open to the public for a minimum of 30 hours per week except physicians (as defined in section 1848(j) (3) of the Act) or physical and occupational therapists or a DMEPOS supplier working with custom made orthotics and prosthetics.

DMEPOS suppliers have the option to disclose the following statement to satisfy the requirement outlined in Supplier Standard 16 in lieu of providing a copy of the standards to the beneficiary.

The products and/or services provided to you by (supplier legal business name or DBA) are subject to the supplier standards contained in the Federal regulations shown at 42 Code of Federal Regulations Section 424.57(c). These standards concern business professional and operational matters (e.g. honoring warranties and hours of operation). The full text of these standards can be obtained at <http://www.ecfr.gov>. Upon request we will furnish you a written copy of the standards.



NOTICE OF USES – PROTECTED HEALTH INFORMATION

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

In accordance with the requirements of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), the organization is required to inform you of its practices in relation to the protected health information that it maintains about you. HIPAA mandates minimum standards that a covered entity such as the organization must maintain in relation to your protected health information. This Notice of Uses is being provided to help you understand how the organization meets these minimum standards. It is also meant to inform you of the ways that the organization may use the personal information it collects about you and how it may disclose it.

UNDERSTANDING YOUR PROTECTED HEALTH INFORMATION

When you receive care from a healthcare provider, a record of that treatment is made. This record will typically contain information on your diagnosis, treatment, and future plan of treatment and is often collectively referred to as your medical record. This medical record includes protected health information and lays the foundation for determining your plan of care and treatment and allows for a successful means of communication between all healthcare professionals that contribute to your care.

HIPAA protects information found in your medical record from disclosure without your authorization. The information protected by HIPAA includes:

1. Any information related to your past, present or future physical or mental health;
2. The past, present or future payment for health services you have received;
3. The specific care that you have received, are receiving or will receive;
4. Any information that identifies you as the individual receiving the care; and
5. Any information that someone could reasonably use to identify you as receiving the care.
6. Any genetic information about an individual for underwriting purposes.

This information is referred to as Protected Health Information throughout this Notice.

TREATMENT, PAYMENT AND HEALTHCARE OPERATIONS

As a Covered Entity, the organization is required to inform you of how it may use your protected health information. In providing treatment to you, the organization will use your protected health information for the purposes of treatment, payment and healthcare operations.

Treatment - As it pertains to the organization, treatment means providing to you drugs, medications, supplies and durable medical equipment services as ordered by your physician. Treatment also includes coordination and consultation with your physician and other health care providers. As the organization provides these services to you, information obtained during this process will be recorded in your medical record. The organization will use this information, in coordination with your physician, to determine the best course of treatment for you.

Payment - Payment purposes consist of activities required to obtain reimbursement from your insurance carrier for the services ordered by your physician and provided to you by the organization. This includes, but is not limited to, copay assistance, eligibility determination, pre-certification, billing and collection activities, obtaining documentation required by your insurer, and when applicable, disclosure of limited information to consumer reporting agencies.

Healthcare operations - Operations can include, but are not limited to, review of your protected health information by members of the organization's professional healthcare staff to ensure compliance with all federal and state regulations. This information will then be utilized to continually improve the quality and effectiveness of the services provided to you by the organization. Healthcare operations also include the organization's business management and general administrative activities.

OTHER USES AND DISCLOSURES

In order to release information contained in your medical record for purposes other than treatment, payment or healthcare operations, the organization must obtain a specific signed authorization from you. You may revoke such authorization at any time, except to the extent the organization has taken action in reliance on the authorization.

There are a limited number of other uses and disclosures of protected health information that do not require a specific authorization from you. The organization may in the following circumstances disclose your protected health information.

1. The organization may disclose limited health information about you to notify local agencies (i.e. power, gas, phone company, and emergency medical services), in the event of an emergency (i.e. flood, hurricanes, etc.), of your need for life sustaining equipment or assistance in evacuation due to your medical condition.
2. The organization may disclose to a member of your family, other relative, or a close personal friend, or any other person identified by you, the protected health information directly relevant to such person's involvement with your care or payment related to your health care.
3. The organization may disclose protected health information to others as required by law.
4. The organization may disclose protected health information for certain public health activities and purposes.
5. The organization may disclose protected health information to a legally-authorized government authority, such as a social service or protective services agency, if we reasonably believe you are a victim of abuse, neglect or domestic violence.
6. The organization may disclose protected health information for law enforcement purposes and in response to court orders or subpoenas.
7. The organization may disclose protected health information to agencies authorized by law to conduct health oversight activities, including audits, investigations, licensing and similar activities.
8. The organization may disclose protected health information to attorneys, accountants, and others acting on behalf of the organization to respond to lawsuits and legal actions, provided they have signed written contracts agreeing to safeguard the confidentiality of the information.

9. The organization may disclose protected health information to the Secretary of the Department of Health and Human Services for HIPAA Rules compliance and enforcement purposes.
10. The organization may disclose protected health information to perform health research.
11. The organization may disclose protected health information to respond to organ and tissue donation requests.
12. The organization may disclose protected health information to work with a medical examiner or funeral director.
13. The organization may disclose protected health information to address workers' compensation, law enforcement and other government requests.

YOUR RIGHTS AS A PATIENT OF THE ORGANIZATION

In accordance with HIPAA you have the following rights in relation to your protected health information.

1. You may request, in writing, additional restrictions to the use or disclosure of your protected health information; however, the organization is not required to agree to the requested restrictions.
1. You have the right to request amendments to your medical record.
2. You have the right to obtain a copy of this Notice of Uses.
3. You have the right of access to inspect and obtain a copy of your medical record in a timely manner, subject to certain limitations.
4. You have the right to obtain an accounting of disclosures of your medical record for purposes other than treatment, payment and healthcare operations.
7. You have the right to request communications of your medical record by alternative means (i.e. electronically) or at alternative locations.
5. You have the right to revoke authorization to use or disclose your protected health information except to the extent that action has already occurred.

RESPONSIBILITIES OF THE ORGANIZATION

In accordance with HIPAA, the organization is required to:

1. Maintain the confidentiality of your protected health information. Your state laws may provide more protection than the federal laws and, in that case, we will abide by the more restrictive statute.
2. Provide you with notice of our legal obligations and privacy practices regarding information it may accumulate about you and is obligated to abide by the terms of this notice.
3. Notify you if it is unable to agree to a requested restriction, and make every effort to accommodate reasonable requests for communication of health information by alternative means.
4. Post its Notice of Uses on its website.
5. Notification of Breach of PHI to affected individuals of any unauthorized acquisition, access, use, or disclosure of unsecured PHI without unreasonable delay but not later than 60 calendar days after discovery.



Please be advised that in addition to these responsibilities, the organization reserves the right to change the terms of its Notice of Uses and make those changes applicable to all protected health information maintained at that time. If there is a change to its Notice of Uses, it will provide you with a revised notice to the most recent address you have supplied to the organization.

The organization will not use or disclose your protected health information without your authorization, except as described in this notice.

FOR MORE INFORMATION OR TO REPORT A PROBLEM

If you have questions, would like additional information or, if you suspect misuse of your protected health information and believe that your rights have been violated, you may, without fear of retaliation, contact:

Privacy Officer
320 South Polk Street, Suite 200
Amarillo, TX 79101
1 (800) 658-6146

Or

The Office for Civil Rights
U.S. Department of Health & Human Services
200 Independence Avenue SW
Room 509F HHH Building
Washington D.C. 20201
1 (800) 368-1019



PATIENT BILL OF RIGHTS AND RESPONSIBILITIES

PATIENT RIGHTS & RESPONSIBILITIES

To ensure the finest care possible, as a patient receiving our pharmacy services, you should understand your role, rights and responsibilities involved in your plan of care.

Patient Rights [DRX2-2A]

- To confidentiality and privacy of all information contained in the client/patient record and of Protected Health Information; PHI will only be shared in accordance with state and federal law [PM 3-1 ai] [DRX2-5A]
- To identify the program's staff members by name and job title, and to speak with a supervisor if requested [PM 3-1 aii]
- To speak to a healthcare professional [PM 3-1 aiii]
- To receive information about the PMP [PM 3-1 aiv]
- To decline participation or dis-enroll at any point in time [PM 3-1 av]
- To be fully informed in advance about care/service to be provided, including the disciplines that furnish care and the frequency of visits, as well as any modifications to the plan of care [DRX2-1A]
- To be informed in advance of care/service being provided, of the charges, including payment for care/service expected from third parties and any charges for which the client/patient will be responsible [DRX3-4B]
- To receive information about the scope of services that the organization will provide and specific limitations on those services [DRX2-1A]
- To participate in the development and periodic revision of the plan of care [DRX5-4A]
- To refuse care or treatment after the consequences of refusing care or treatment are fully presented [DRX2-6A]
- To be informed of client/patient rights under state law to formulate an Advanced Directive, if applicable [DRX2-6A]
- To have one's property and person treated with respect, consideration, and recognition of client/patient dignity and individuality [DRX2-2B]
- To be able to identify visiting personnel members through proper identification [DRX2-2B]
- To be free from mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of client/patient property [DRX2-3A]

This policy may contain information that is confidential and proprietary. Do not disclose this policy externally without authorization from the owner of the policy.



PATIENT BILL OF RIGHTS AND RESPONSIBILITIES

- To voice grievances/complaints regarding treatment or care, lack of respect of property or recommend changes in policy, personnel, or care/service without restraint, interference, coercion, discrimination, or reprisal [DRX2-4A]
- To have grievances/complaints regarding treatment or care that is (or fails to be) furnished, or lack of respect of property investigated [DRX2-4A]
- To be advised on agency's policies and procedures regarding the disclosure of clinical records [DRX2-5A]
- To choose a health care provider, including choosing an attending physician, if applicable [DRX2-2B]
- To receive appropriate care without discrimination in accordance with physician orders, if applicable [DRX2-2B]
- To be informed of any financial benefits when referred to an organization [DRX2-2B]
- To be fully informed of one's responsibilities [DRX2-2B]

For further information about this policy or any concerns related to your rights, you may contact VytOne's Confidential Compliance Hotline at 1-844-362-5918.

Patient Responsibilities [DRX2-2A.01]

- To provide accurate medical, clinical, and contact information [PM 3-1 bi] [DRX2-2A.01]
- To submit forms that are necessary to receive services [DRX2-2A.01]
- To notify their treating provider of their participation in the PMP, if applicable [PM 3-1 bii] [DRX2-2A.01]
- To maintain any equipment provided, if applicable [DRX2-2A.01]
- To notify the organization of any concerns about the care or services provided [DRX2-2A.01]

This policy may contain information that is confidential and proprietary. Do not disclose this policy externally without authorization from the owner of the policy.

