

Specialty Pharmacy Fact Sheet

Specialty pharmacies in the **United States** distribute specialty drugs, which are medications defined as complex, expensive, difficult to get and adhere to, and often used to treat rare diseases, such as Waldenstrom's macroglobulinemia (WM). Ideally, the specialty pharmacy provides individualized care that maximally benefits the patient's medication experience. As part of this individualized attention, specialty pharmacies offer services above and beyond those typically offered at the retail pharmacy level as part of their standard of care. These services may include the following:

- 24-hour access to pharmacists
- Adherence management
- Benefits investigation
- Communication and follow-up with the physician
- Dispensing of specialty pharmaceuticals and shipping coordination
- Enrollment in patient assistance programs
- Financial assistance
- Patient education and counseling for adverse effects from medication
- Patient monitoring for safety and efficacy
- Payer and/or manufacturer reporting
- Proactive patient outreach for prescription refill and renewal
- Prior authorization assistance

Specialty medicines can be just as complex as the medical conditions they treat. Because of this complexity, the pharmacies that dispense them need to be just as special. Drug manufacturers decide on the distribution of their drugs, and they usually choose specialty pharmacies when a drug matches the definition of a specialty medication. If a manufacturer chooses to distribute its drug through a specialty pharmacy, then only a specialty pharmacy can dispense the medication — a retail pharmacy cannot dispense a specialty drug. Most of today's oral therapies for cancers, including those prescribed or in clinical trials for WM (such as ibrutinib, ixazomib, acalabrutinib, zanubrutinib, pirtobrutinib, everolimus, and venetoclax) meet the above criteria for specialty medicines. This means that the specialty pharmacy is actually a member of the health care team similar to your provider's office.

What Are the Benefits of Using a Specialty Pharmacy?

The specialty pharmacy's team helps you every step of the way, including answering your questions about your medication, helping you with financial assistance, and ensuring that you get your medicine quickly and safely. A specialty pharmacy will see that you get your medication on time, that you are fully educated on how to take it and how to store it, and that you know what to expect as far as side effects are concerned. The specialty pharmacy has nurses who can help you with any side effects you may experience. They will coach you and remind you about how to take your medication. The clinical team is typically available 24 hours a day/7 days a week to answer any questions or concerns you might have. They can be a "link" between you and your hematology/oncology team while you are on an oral specialty drug.

How Do I Find a Specialty Pharmacy?

Most hematologists/oncologists have a "go-to" specialty pharmacy that they trust. This relationship has been built over time, and the provider trusts the pharmacists and nurses at the specialty pharmacy to take good care of their patients. Usually, there is good, proactive communication between your doctor

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and your specialty pharmacy. If you have a preferred specialty pharmacy in mind, either because you have received medications from it before or know someone who has, you can request that prescriptions be sent to that pharmacy. If you have a preferred specialty pharmacy, you should tell your hematology/oncology provider.

Limited Distribution Network (LDN)

A biopharmaceutical manufacturer will often place its specialty medications in a limited distribution network (LDN), meaning that only a select few specialty pharmacies can handle and dispense their medication. They want patients taking their therapy to have special attention and support. By limiting the number of pharmacies that have access, they can better ensure that patient care is a priority.

Insurance Coverage

It is common for insurers to decide which specialty pharmacy will handle your prescription. This is more likely when the distribution network is larger (i.e., many specialty pharmacies have access to that therapy). However, in situations like the limited distribution networks mentioned above, insurers are less likely to mandate where your prescription must be filled. On very rare occasions, where the patient population is limited, biopharmaceutical manufacturers may decide to have an “exclusive specialty pharmacy,” which would result in your medication being filled only by that one pharmacy.

Although each specialty pharmacy is a bit different, these are the steps that most take to support patients and providers:

Benefits Investigation

When your prescription is sent to a specialty pharmacy by your hematologist/oncologist, staff members at the specialty pharmacy will quickly determine if your medication is covered by your insurance.

Prior Authorization

The specialty pharmacy will then work with your insurance to decide if your medication requires a prior authorization by that insurance company, and if so, the specialty pharmacy will reach out to your hematologist/oncologist to initiate that process.

Appeals

If for some reason your prior authorization is denied and your medical provider feels that the medicine is still your best option, the specialty pharmacy will help gather scientific data to share with your provider. Your medical provider can then use the data to appeal your denial.

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Financial Aid

If you cannot afford your co-pay or you are unable to afford your medicine, the staff at your specialty pharmacy will assist you in applying for free drug programs and/or help you apply for co-pay assistance, track any approved funds, and apply them to your bill with each refill.

Getting Your Medication

Before your medication is shipped, you will be contacted by your specialty pharmacy to ensure that all of the patient access services listed above have been completed and that the specialty pharmacy has the correct shipping address for your medicine. If you are going on vacation or to a second home, the specialty pharmacy can ship your medication to an alternate address. If you plan to take an extended vacation that requires refilling your medication before the refill is due, contact the specialty pharmacy so that it can obtain an insurance override and ensure that your refill is shipped before you depart for your trip. Note: The specialty pharmacy typically contacts you in advance of your next refill with adequate time allowed for shipping. However, if you don't hear from the pharmacy within 4-5 days of your next refill, it is advisable to contact the pharmacy as a reminder. If you are out of refills, a new prescription may be needed. The pharmacy will reach out to the physician's office for a new prescription, but it is helpful for the patient to also make this contact.

Clinical Counseling

Most of the medications used to treat WM are complex in nature, with specific education needed for taking your medication, side effects, and potential interactions with other drugs. The specialty pharmacy may have a pharmacist reach out to you for additional education and counseling and to ensure your safety in taking your new medication. In many cases, patients prefer to have a friend or family member on the phone with them for that call to take notes and document any special needs. As a patient, you will also have the opportunity to ask the pharmacist any questions that you might have about your new therapy.

Adherence and Side Effect Management

Most specialty pharmacies will have a nurse reach out to you a few days after you start your medication. During that call, the nurse will ensure that you are taking the medication the way that your provider intended for you to take it. These nurses understand that anytime you start a new medication for your WM, it can be overwhelming and difficult to remember everything you heard on the first call. The nurse will reiterate what the pharmacist told you and answer any new questions that you may have. The nurse will also review potential side effects of your therapy and give you advice and tips to manage any side effects that you may be experiencing. If there is anything about your medication or side effects that your provider needs to be made aware of, the nurse can also offer to communicate that information back to your provider on your behalf.

Some treatments are associated with special nursing programs when a nurse at the pharmacy will reach out to you multiple times over the course of your therapy to ensure that you are feeling well and do not have any questions. If at any time you feel that these calls are not necessary, you can opt out of receiving them. It is the clinical staff's goal that you continue your medication(s) as long as it is beneficial to your health and that you have the best possible experience with your medication.

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Pharmacist On-Call

Once you start your medication, the specialty pharmacy will provide you with a toll-free number to call the pharmacy and speak to its clinical staff at any time. Nurses are typically available during regular business hours, and pharmacists are on call 24 hours a day, year-round. If the pharmacy is closed, the after-hours pharmacist will be available to answer questions about your therapy or side effects that you may be experiencing.

Collaboration with Your Health Care Team

Specialty pharmacies, which once occupied only a small niche, have become a rapidly increasing presence in health care. Collaborations between specialty pharmacies, retail pharmacies, hospitals, and manufacturers are becoming more commonplace. These collaborations can enhance patient access to specialty medications while providing one-on-one services that only a specialty pharmacy can provide, thereby improving patient care. Your physician still remains the primary resource for discussions about drug side effects and dosing.

Specialty Pharmacies and Waldenstrom's Macroglobulinemia (WM)

Patients with WM who have utilized a specialty pharmacy have noted that the following benefits are the most useful:

- Pharmacists may be more knowledgeable about the drugs since they have a limited focus on a few drugs
- Drug usage is monitored
- Drugs are delivered to your home
- Financial counseling is provided

In addition to specialty pharmacies, the pharmacies that are associated with large medical centers or cancer hospitals may dispense the oral therapies that the medical team prescribed for treatment of WM. Some physicians may order the treatments for WM and supply their patients with their medications directly. Several therapies are available as intravenous (IV) infusions and/or injections just under the skin (subcutaneous) that are administered in the hospital, clinics, or medical centers. Specialty pharmacy information for those therapies used to treat WM that are preferred, recommended, or useful in certain circumstances per NCCN® (National Cancer Network©) Guidelines for WM, Version 1.2023, July 6, 2022, are presented below in *Table 1*. The National Comprehensive Cancer Network is an alliance of 32 cancer centers in the United States, most of which are designated by the National Cancer Institute as comprehensive cancer centers. It is a non-profit organization.

Certain drugs are only carried at specific specialty pharmacies for monitoring purposes. The five major specialty pharmacy providers (SPPs) for the therapies used to treat WM are listed below:

Biologics by McKesson <https://biologics.mckesson.com> ph:1-800-850-4306 fax:1-800-823-4506

Onco360 www.onco360.com ph: 1-877-662-6633 fax:1-877-662-6355, 24-hour call line

Optum <https://specialty.optumrx.com> ph:1-855-427-4682 fax:1-877-342-4596 (Avella and Diplomat

specialty pharmacies are now part of Optum Specialty Pharmacy)

CVS Specialty Pharmacy www.cvsspecialty.com ph:1-800-237-2767

Walgreens Alliance Rx www.alliancerxwp.com/specialty-pharmacy ph:1-866-515-1355

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Table 1. Pharmacy information for therapies used to treat WM that are preferred, recommended, or useful in certain circumstances per NCCN® (National Comprehensive Cancer Network®) Guidelines, Version 1.2023, July 6, 2022 (continued on next page)

Drug Generic Name (Trade Name(s))	Traditional Pharmacy (Oral Medication)	Specialty Pharmacy (Oral Medication)	Into a Vein (Intravenous Infusion)	Injection Under the Skin
Acalabrutinib Calquence® from AstraZeneca		Yes-Biologics by McKesson, Onco 360, Optum (Avella and Diplomat)		
Bendamustine hydrochloride (Treanda®, Bendeka® from Teva Belrapzo® from Eagle, and others			Yes	
Bortezomib (Velcade® from Takeda, Chemobort® from Cytogen, Bortecad® from Cadila), and others			Yes	Yes
Carfilzomib (Kyprolis® from Amgen)			Yes	Yes
Cladribine (Leustatin™)			Yes	
Cyclophosphamide (Cytoxan®, Endoxan®, Lysolizedblastin Cytoxan®, Neosar®, Revimmune Cycloblastin®, Procytox in Canada), and others	Yes		Yes	
Dexamethasone (Decadron®) and others	Yes		Yes	Yes
Doxorubicin (Adriamycin®, Rubex®)			Yes	
Everolimus (Afinitor® from Novartis and others	Yes	Yes-CVS Specialty Pharmacy, Walgreens Alliance Rx		
Fludarabine (Fludara®, Oforta®)	Yes		Yes	

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Drug Generic Name (Trade Name(s))	Traditional Pharmacy (Oral Medication)	Specialty Pharmacy (Oral Medication)	Into a Vein (Intravenous Infusion)	Injection Under the Skin
Ibrutinib (Imbruvica® from Pharmacyclics, Janssen Biotech)		Yes-Biologics by McKesson, Onco 360, Optum (Avella and Diplomat)		
Ixazomib (Ninlaro® from Takeda)		Yes-CVS Specialty Pharmacy, Accredo, Walgreens Alliance Rx, Axiom, Biologics by McKesson		
Ofatumumab (Arzerra®, from Novartis)		Yes-CVS Specialty Pharmacy	Yes	
Prednisone	Yes			
Rituximab Rituximab and hyaluronidase (injection) (Rituxan Hycela® injection from Genentech, Rituxan SC in Canada) Biosimilars: Truxima® Ruxience®, Rixathon® (in Europe) and others			Yes	Yes
Venetoclax (Venclexta™, Venclexto™, Venclyxto™)		Yes-Biologics by McKesson, Onco 360, Optum (Avella and Diplomat)		
Vincristine (Vincasar PFS® from Teva)			Yes	
Zanubrutinib (Brukinsa® from BeiGene)		Yes-Biologics by McKesson, Onco 360		

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About the IWMF

The IWMF Vision Statement

A world without WM (Waldenstrom's macroglobulinemia).

The IWMF Mission Statement

Support and educate everyone affected by Waldenstrom's macroglobulinemia (WM) to improve patient outcomes while advancing the search for a cure.

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The information presented here is intended for education purposes only. It is not meant to be a substitute for professional medical advice. Patients should use the information provided in full consultation with, and under the care of, a professional medical specialist with experience in the treatment of WM. We discourage the use by a patient of any information contained here without disclosure to his or her medical specialist.

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