

April 2022

medical benefit specialty drug update **bulletin**

Specialty Drug Program Updates for UnitedHealthcare Commercial, Community Plan, Medicare Advantage, and Individual & Family Plans

Review the following tables to determine changes to our specialty medical injectable drug programs.

SPECIALTY MEDICAL INJECTABLE DRUGS ADDED TO REVIEW AT LAUNCH

Drug Name	UnitedHealthcare Commercial	UnitedHealthcare Community Plan	UnitedHealthcare Medicare Advantage	UnitedHealthcare Individual & Family	Treatment Uses
Korsuva™ (difelikefalin)	X	X		X	Indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis (HD).

To view the **UnitedHealthcare Commercial Plan** Review at Launch Medication List, go to UHCprovider.com > Policies and Protocols > Commercial Policies > Medical & Drug Policies and Coverage Determination Guidelines for UnitedHealthcare Commercial Plans > *Review at Launch for New to Market Medications* > [Review at Launch Medication List](#).



To view the **UnitedHealthcare Community Plan** Review at Launch Drug List Plan, go to UHCprovider.com > Policies and Protocols > Community Plan Policies > Medical & Drug Policies and Coverage Determination Guidelines for Community Plan > *Review at Launch for New to Market Medications* > [Review at Launch Medication List](#).

For **UnitedHealthcare Medicare Advantage**, Review at Launch drugs are added as Review at Launch Part B Medications in the *Medications/Drugs (Outpatient/Part B) Coverage Summary*. To view the summary, go to UHCprovider.com > Policies and Protocols > Medicare Advantage Policies > Coverage Summaries for Medicare Advantage Plans > [Medications/Drugs \(Outpatient/Part B\) – Medicare Advantage Coverage Summary](#) > *Attachment A: Guideline 5 – Other Examples of Specific Drugs/Medications*.

To view the **UnitedHealthcare Individual & Family Plan** Review at Launch Medication List, go to UHCprovider.com > Policies and Protocols > For Exchange Plans > Medical & Drug Policies and Coverage Determination Guidelines for UnitedHealthcare Individual Exchange Plans > *Review at Launch for New to Market Medications* > [Review at Launch Medication List](#)

UPDATES TO DRUG PROGRAM REQUIREMENTS AND DRUG POLICIES

Drug Name	Effective Date	UnitedHealthcare Commercial	UnitedHealthcare Community Plan	UnitedHealthcare Medicare Advantage	UnitedHealthcare Individual & Family	Treatment Uses	Summary of Changes
Apretude™	7/1/2022	X	X		X	Long-acting injectable for the treatment of pre-exposure	• Add Notification/Prior Authorization

(cabotegravir extended-release injectable suspension)						prophylaxis (PrEP) to reduce the risk of HIV-1 infection in adolescents and adults.	<ul style="list-style-type: none"> For Commercial, add Site of Care For Commercial and C&S, add Preferred Product: oral PrEP; Aprelude™ will be non-preferred.
Botulinum toxins A and B - Dysport®, Xeomin®, Botox®, Myobloc®	7/1/2022	X				Neuromuscular blocker/acetylcholine release inhibitor used in many neurological, neuromuscular, and urological conditions such as migraine, spasticity, strabismus, torticollis, urinary incontinence, and overactive bladder.	<ul style="list-style-type: none"> Add Notification/Prior Authorization
Cabenuva™ (cabotegravir/rilpivirine)	7/1/22		X Maryland only			Used to treat human immunodeficiency virus type 1 (HIV-1) infection in adults to replace a current antiretroviral regimen in those who are virologically suppressed on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.	<ul style="list-style-type: none"> Add Notification/Prior Authorization
Carvykti™ (ciltacabtagene autoleucel)	7/1/2022	X	X	X	X	For the treatment of relapsed and/or refractory multiple myeloma after 3 or more lines of previous therapy	<ul style="list-style-type: none"> Add Notification/Prior Authorization Managed by Optum Transplant Network
Cimzia® (certolizumab pegol)	7/1/2022		X California, Kentucky, Louisiana, and Ohio only			For the treatment of inflammatory conditions such as Crohn's Disease, psoriatic arthritis, and rheumatoid arthritis.	<ul style="list-style-type: none"> Add Notification/Prior Authorization
Entyvio® (vedolizumab)	7/1/22			X		For the treatment of moderate to severe ulcerative colitis and Crohn's disease in patients who have had an inadequate response to conventional therapy.	<ul style="list-style-type: none"> Add Notification/Prior Authorization
Intravitreal Vascular Endothelial Growth	5/1/2022			X		For the treatment of ophthalmologic conditions	<ul style="list-style-type: none"> Added to the Medicare Part B Step Therapy Programs

Factor (VEGF) Inhibitors – Byooviz™ (ranibizumab-nuna), Susvimo™ (ranibizumab), Vabysmo® (faricimab-svoa)						such as Neovascular (wet) age-related macular degeneration (AMD) and macular edema.	policy as non-preferred medications for the treatment of AMD
Leqvio® (inclisiran)	7/1/2022	X	X	X	X	Indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C).	<ul style="list-style-type: none"> Add Notification/Prior Authorization For Commercial, add Site of Care For Commercial and C&S, add Preferred Product: PCKS9 inhibitor; Leqvio® will be non-preferred.
Ocrevus® (ocrelizumab)	7/1/22			X		For the treatment of primary progressive or relapsing forms of multiple sclerosis.	<ul style="list-style-type: none"> Add Notification/Prior Authorization
Orencia® (abatacept)	7/1/22			X		For the treatment of inflammatory conditions such as psoriatic arthritis and rheumatoid arthritis.	<ul style="list-style-type: none"> Add Notification/Prior Authorization
Purified Cortrophin™ Gel (repository corticotropin)	7/1/2022	X	X		X	For the treatment of Infantile Spasm or Opsoclonus Myoclonus.	<ul style="list-style-type: none"> Add Notification/Prior Authorization For Commercial, add Site of Care
Synagis® (palivizumab)	7/1/2022		X Louisiana and Ohio only			For the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in high-risk pediatric patients.	<ul style="list-style-type: none"> Add Notification/Prior Authorization
Trogarzo® (ibalizumab)	7/1/2022		X Maryland only			For the treatment of human immunodeficiency virus type 1 (HIV-1) infection, in combination with other antiretroviral medications, in treatment experienced adults with multidrug resistant HIV-1 infection.	<ul style="list-style-type: none"> Add Notification/Prior Authorization



Uplizna® (inebilizumab)	7/1/2022		X Maryland only			Treatment for neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.	<ul style="list-style-type: none"> Add Notification/Prior Authorization
Vyvgart™ (efgartigimod)	7/1/2022	X	X	X	X	For the treatment of generalized myasthenia gravis in adults who test positive for anti-acetylcholine receptor (AChR) antibody.	<ul style="list-style-type: none"> Add Notification/Prior Authorization For Commercial, add Site of Care
Xolair® (omalizumab)	7/1/2022		X			For the treatment of moderate to severe persistent asthma, chronic idiopathic urticaria, and nasal polyps.	<ul style="list-style-type: none"> Add Notification/Prior Authorization

Upon prior authorization renewal, the updated policy will apply. UnitedHealthcare will honor all approved prior authorizations on file until the end date on the authorization or the date the member’s eligibility changes. You don’t need to submit a new notification/prior authorization request for members who already have an authorization for these medications on the effective date noted above.

Note: Certain specialty medical injectable drug programs and updates will not be implemented at this time for providers practicing in Rhode Island, with respect to certain commercial members, pursuant to the Rhode Island regulation: 230 -RICR-20-30-14. UnitedHealthcare encourages providers practicing in Rhode Island to call in to confirm if prior authorization is required. This exception does not apply to Medicaid and Medicare.

New Medical Benefit Therapeutic Equivalent Medications - Excluded Drugs Policy for UnitedHealthcare Commercial Members – Effective July 1, 2022

We’re committed to providing the members we insure with access to high-quality medications at the lowest possible cost. In some cases, there are lower-cost options available for coverage when there are multiple medications that are used to treat the same condition for your patients. Due to the results of a recent clinical review & the availability of lower cost alternatives, we are changing coverage for some UnitedHealthcare Commercial members.

Who’s Affected

These changes affect UnitedHealthcare Commercial fully insured plan members, including members of affiliate plans, such as UnitedHealthcare of the Mid-Atlantic, UnitedHealthcare Oxford and Neighborhood Health Partnership. In the following states, a clinical review will be made available for fully insured members according to applicable state requirements:

- California
- Colorado
- Connecticut
- Maryland
- New Jersey
- New York
- Virginia



Important Points

- We will honor all approved prior authorizations for the non-covered medication until the end date on the authorization or the date the member’s eligibility changes.
- If you administer the non-covered medication to your patient after the prior authorization expires, it will not be covered.
- This change applies whether a member is new to therapy or has already been receiving the medication.
- We may require a notification/prior authorization for the other suggested medication options listed.
- Coverage reviews conducted as part of our prior authorization process for the medication options above may also evaluate the site of care for the administration of the medication. Coverage determinations will consider whether the patient has a need for more intensive service.
- We may require medication sourcing for other medication options listed as part of the UnitedHealthcare Provider Administrative Guide. Outpatient providers may not be able to “buy and bill” for other medication options listed. We have contracted pharmacies for the distribution of these medications.
- Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service.

This table summarizes the changes we’re implementing beginning July 1, 2022, including suggested alternatives.

Drug Class	Excluded Medication		Other Options		UnitedHealthcare Commercial
Immune Globulin	Asceniv™ Cutaquig® Panzysa®		Bivigam® Cuvitru® Carimune® Flebogamma® Gammagard® Gammaked™ Gammaplex®	Gamunex-C® Hizentra® Hyqvia® Octagam® Privigen® Xembify®	7/1/22 Fully Insured
Sodium Hyaluronate	Gel-One® Genvisc® 850 Hyalgan® Hymovis® Monovisc® Orthovisc®	Supartz FX® SynoJoynt™ Synvisc® Synvisc One® Triluron® TriVisc® Visco-3™	Durolane® Euflexxa® Gelsyn-3®		

New and Updated Procedure Codes for Injectable Medications – Effective April 1st, 2022

Effective April 1, 2022, new procedure codes were created for certain drugs due to updates from the Centers for Medicare & Medicaid Services (CMS). Correct coding rules dictate that assigned and permanent codes should be used when available. The following injectable medications will have new codes:

- **Byooviz™** (ranibizumab-nuna) - Q5124
- **Nexviazyme™** (avalglucosidase alfa-ngpt) - J0219
- **Saphnelo™** (anifrolumab-fnia) - J0491



- **Ryplazim**[®] (plasminogen, human-tvmh) - C9090

Updates for UnitedHealthcare Freedom Plans medical drug policies, medication sourcing requirements and prior authorization requests

Medical Drug Policies

Effective for dates of service on or after July 1, 2022, we're aligning the UnitedHealthcare Freedom Plans to the existing UnitedHealthcare commercial medical drug policies:

- UnitedHealthcare requires providers to use a lower-cost specialty medication before coverage for a clinically similar, higher-cost medication for certain specialty medications. Preferred product strategies require care providers to prescribe clinically appropriate and lower-cost medications; these strategies can be found in their corresponding medical drug policies by searching on the individual drug policies within the [Medical & Drug Policies and Coverage Determination Guidelines list](#).
- As part of our prior authorization process, coverage reviews will evaluate the site of care for the administration of certain drugs. Coverage determinations will take into account whether the patient has a need for more intensive services. The utilization review guideline we use to help facilitate our site of care medical necessity determinations for services is available at UHCprovider.com/policies.

Medication Sourcing

UnitedHealthcare Freedom Plans specialty pharmacy requirement July 1, 2022

To support the provider/patient relationship in managing rare and complex chronic conditions, we require care providers who participate in UnitedHealthcare commercial plans to follow specialty pharmacy requirements when obtaining certain specialty medications covered under the member's medical benefit. Effective for dates of service on or after July 1, 2022, we're aligning the UnitedHealthcare Freedom Plans to the existing UnitedHealthcare commercial specialty pharmacy requirement.

How this affects UnitedHealthcare Freedom Plan care providers & hospitals

We'll require participating care providers & hospitals to obtain certain specialty medications for UnitedHealthcare Freedom Plan members from indicated specialty pharmacies, unless otherwise authorized by UnitedHealthcare. If the specialty drug is obtained through the indicated specialty pharmacy, the specialty pharmacy will bill UnitedHealthcare directly for the drugs under the member's medical benefit. The drugs on the [Specialty Pharmacy Requirements Drug List](#) are subject to this requirement. If the specialty drug is obtained through the indicated specialty pharmacy, the specialty pharmacy will bill UnitedHealthcare directly for the drug under the member's medical benefit. Care providers may not seek any reimbursement from the member for the drug.

Important points

- Hospitals will only need to bill UnitedHealthcare the appropriate code for administration of the medication and not for the medication itself
- This protocol doesn't apply when Medicare or another health benefit plan is the primary payer and UnitedHealthcare is the secondary payer
- The list of specialty medications is subject to change upon a 90-day written notice

If you have questions about how this applies to you or your facility, please contact your network contract manager.

UnitedHealthcare Freedom Plans injectable medication prior authorization process change for certain specialty drugs

Effective July 1, 2022, Optum, an affiliate company of UnitedHealthcare, will start managing prior authorization requests for certain medical benefit medications for UnitedHealthcare Freedom Plan members. This is currently in place for UnitedHealthcare commercial plan members.

Requesting prior authorizations using the Specialty Guidance Program tool in the [UnitedHealthcare Provider Portal](#) is designed to reduce the turnaround time for a determination by leveraging auto-decisioning technology that results in over 50%* of all cases approved in real time. The system will document clinical requirements during the intake process and prompt you to provide responses to the clinical criteria questions.

How to request prior authorization



Submit prior authorization requests online using the Specialty Guidance Program tool.

- Sign in to the [UnitedHealthcare Provider Portal](#) using your One Healthcare ID
- Select the "Prior Authorization" tab in the menu, and you will be redirected to the prior authorization tool
- Select "Submission & Status" under the **Specialty Pharmacy Transaction** header
- Be sure to attach medical records, if prompted
- You can also **call 888-397-8129** for help with a prior authorization.

Please use this online process when requesting notification/prior authorization for a specialty medication listed under the injectable medications section of the [Enterprise Prior Authorization List](#) or a medication that is required to be provided from an indicated specialty pharmacy, as noted below.

You'll need to request a prior authorization once an existing authorization expires or if you change the therapy. Changes in therapy include place of therapy, dose or frequency of administration. If you have already obtained an authorization for a member, that authorization is still active until the original expiration date.

Learn more about the [Specialty Guidance Program](#).