LEQVIO® (inclisiran) injection 284 mg/1.5 mL

Buy-and-bill process checklist

The checklist below includes common steps that organizations may consider that can help manage LEQVIO® acquisition through buy-and-bill.

This information is provided for educational purposes only and is not a guarantee of coverage or reimbursement. This checklist is not meant to be exhaustive of all steps that may need to be considered in order to acquire through buy-and-bill. It is the sole responsibility of the health care provider to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

1 Verify benefits

- ☐ Confirm the patient's benefits with their insurance plan
- ☐ Complete the LEQVIO one-page **Start Form** (optional) and submit through the Service Center Portal at **ServiceCenterPortal.com** OR via fax at **877-LEQVIO8 (877-537-8468)**
- ☐ If a Start Form was sent to the Service Center, review Statement of Benefits once your office receives it, usually within 3-5 business days, to understand:
  - If a prior authorization (PA) is required, as well as any plan-specific PA criteria
  - The patient's out-of-pocket costs
  - Methods of acquisition allowed by the health plan
  - Payer site-of-care requirements
  - Billing and coding information
- ☐ Ensure that the patient has met their plan's PA criteria (if applicable) before submitting a PA. PA criteria may vary by plan
- ☐ Discuss out-of-pocket costs with the patient

2 Order LEQVIO

- ☐ Establish an account with accredited distributors before you begin ordering
- ☐ Develop methods for separating buy-and-bill inventory, free drug samples, and specialty pharmacy inventory
- ☐ Finalize storage logistics for LEQVIO. Remember that LEQVIO can be stored at room temperature. Controlled room temperature is 68-77 °F (20-25 °C) with allowable excursions between 59-86 °F (15-30 °C)
- ☐ Prepare to assume financial responsibility for LEQVIO

3 Administer LEQVIO

- ☐ Review the patient's out-of-pocket costs
- ☐ Collect the patient's co-pay or coinsurance according to your practice's billing protocols
- ☐ Administer LEQVIO
- ☐ If a patient is in for their initial dose of LEQVIO, schedule them to come back for another dose in 3 months. After that, plan and schedule the patient's next injection for every 6 months

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4 Submit claim

- [ ] Fill out a CMS-1500 or CMS-1450 (UB-04) form if billing prescribed medications administered in an HCP office or hospital outpatient setting, respectively
- [ ] Understand current commercial and Medicare Advantage contracts
- [ ] Use permanent J-code J1306 for patients who received LEQVIO®.[1] Ensure the JZ modifier is used with the J-code for all claims. You are required to report the JZ modifier on all claims that bill for drugs from single-dose containers that are separately payable under Medicare Part B when there are no discarded amounts[2]
- [ ] If you are a 340B covered entity, ensure you use the TB modifier on all claims for drugs that are acquired through the 340B program for dates of service on or after January 1, 2025[3]
- [ ] Include the appropriate number of billing units for LEQVIO: 284 mg=284 billing units[1] in Box 24G of the CMS-1500 form and Box 46 of the CMS-1450 form
- [ ] Contact the insurance plan directly to check the status of the claim

5 Manage reimbursement

- [ ] Understand your reimbursement rate based on the plan contract and published fee schedules. Review these rates and fee schedules on a quarterly basis in case of an update
- [ ] Allocate an experienced staff member to submit and track reimbursement claims
- [ ] Review the remittance advice—also referred to as an explanation of benefits (EOB)—to ensure appropriate payment once received
- [ ] Establish a reconciliation process to ensure all of the consumed inventory is captured in the billing process
- [ ] Audit claims on a regular basis
- [ ] Make certain that accounts receivable match the accounts payable
- [ ] If your claim is denied, follow the appeals process to help get the claim approved. Contact the LEQVIO Service Center and see the **PA and Appeals Guide** on **LEQVIO-access.com** for more information

Review the buy-and-bill considerations on the next page for additional information when getting started.

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Important considerations when buying and billing for LEQVIO®

5 steps in the buy-and-bill process[4]

		Expected timing
1	Verify patient benefits and what the patient out-of-pocket may be*	Timing dependent on practice process
2	Order LEQVIO†	1–3 days
3	Administer LEQVIO	Timing dependent on practice process
4	Submit claim	Timing dependent on clean submission and payer processes
5	Manage reimbursement‡	

Overview of reimbursement types for drugs reimbursed under the medical benefit

Note: It is the provider's responsibility to research payer contract status and agreements.

Medicare:
- ASP + 6% without sequestration (for Medicare Part B drugs)§
- Fee schedule established by the plan

Commercial:
Reimbursement varies by payer and contract. Some common models:
- WAC + %
- ASP + %
- Fee schedule established by the plan
- Percent of billed charges

Medicaid:
Reimbursement varies by payer and contract.

For questions or support, reach out to your Novartis Access and Reimbursement Expert.

ASP, average sales price; HCP, health care professional; PA, prior authorization; WAC, wholesale acquisition cost.
*Patients with Medicare Advantage (Medicare Part C, Medicaid, or other public insurance coverage) may require precertification or prior authorization as conditions for coverage. The drug manufacturer's service center (patient reimbursement services hub) may provide assistance with benefits investigation and some patients may be eligible for assistance with co-pay costs.
†The HCP will need to store and track drug inventory.
‡Payment will be reduced by sequestration.
§Sequestration applies. 2% reduction to the Medicare allowable.

References: 1. Centers for Medicare & Medicaid Services. CMS HCPCS Application Summaries and Coding Recommendations: First Quarter, 2022 HCPCS Coding Cycle. Accessed September 16, 2024. https://www.cms.gov/files/document/2022-hcpcs-application-summary-quarter-1-2022-drugs-and-biologicals.pdf **2.** Centers for Medicare & Medicaid Services. Medicare program: discarded drugs and biologicals–JW modifier and JZ modifier policy frequently asked questions. Accessed September 16, 2024. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf **3.** Centers for Medicare & Medicaid Services. Revised Part B inflation rebate guidance: Use of the 340B modifier. Published December 14, 2023. Accessed September 16, 2024. https://www.cms.gov/files/document/revised-part-b-inflation-rebate-340b-modifier-guidance.pdf **4.** Fein AJ. Published October 26, 2021. Accessed September 16, 2024. https://www.drugchannels.net/2021/10/follow-vial-buy-and-bill-system-for.html

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