QALSODY® (tofersen) Resource Guide for Practices and Facilities

For Coverage & Continued Treatment With QALSODY

INDICATION

QALSODY® (tofersen) is indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 *(SOD1)* gene. This indication is approved under accelerated approval based on reduction in plasma neurofilament light chain (NfL) observed in patients treated with QALSODY. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Myelitis and/or Radiculitis

Serious adverse reactions of myelitis and radiculitis have been reported in patients treated with QALSODY. Six patients treated with QALSODY experienced myelitis or radiculitis in the clinical studies. Two patients discontinued treatment with QALSODY and required symptomatic management with full resolution of symptoms. In the remaining 4 patients, symptoms resolved without discontinuation of QALSODY. If symptoms consistent with myelitis or radiculitis develop, diagnostic workup and treatment should be initiated according to the standard of care. Management may require interruption or discontinuation of QALSODY.

Please see additional Important Safety Information on page 2 and click for full Prescribing Information.

QALSODY®
(tofersen)
100 mg/15 mL injection

INDICATION AND IMPORTANT SAFETY INFORMATION

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Papilledema and Elevated Intracranial Pressure

Serious adverse reactions of papilledema and elevated intracranial pressure have been reported in patients treated with QALSODY. Four patients developed elevated intracranial pressure and/or papilledema. All patients received treatment with standard of care with resolution of symptoms, and no events led to discontinuation of QALSODY. If symptoms consistent with papilledema or elevated intracranial pressure develop, diagnostic workup and treatment should be initiated according to the standard of care.

Aseptic Meningitis

Serious adverse reactions of aseptic meningitis (also called chemical meningitis or drug-induced aseptic meningitis) have been reported in patients treated with QALSODY. One patient experienced a serious adverse reaction of chemical meningitis, which led to discontinuation of QALSODY. One patient experienced a serious adverse reaction of aseptic meningitis, which did not lead to discontinuation of QALSODY. In addition, nonserious adverse drug reactions of CSF white blood cell increased, and CSF protein increased have also been reported with QALSODY. If symptoms consistent with aseptic meningitis develop, diagnostic workup and treatment should be initiated according to the standard of care.

Adverse Reactions

The most common adverse reactions (≥10% of patients treated with QALSODY and greater than placebo) were pain, fatigue, arthralgia, cerebrospinal fluid white blood cell increased, and myalgia.

Table of Contents

Biogen is committed to QALSODY® (tofersen) patients, their families, and the healthcare professionals (HCPs) that care for QALSODY patients. This guide provides resources to support your practice or facility in navigating the treatment access and procurement processes for patients with amyotrophic lateral sclerosis (ALS) who have been prescribed QALSODY.

Product Fact Sheet

Please see Important Safety Information on page 2 and click for full Prescribing Information.

QALSODY®
(tofersen)
100 mg/15 mL injection

Product Fact Sheet

Company: Biogen

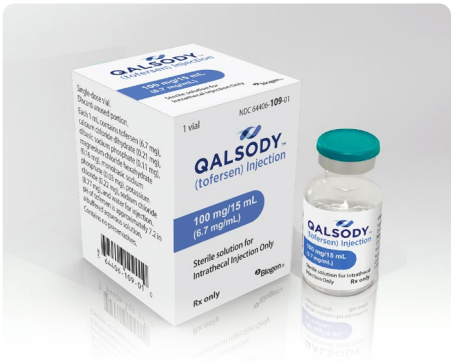
Product Trade Name: QALSODY

Generic Name: tofersen

Product Availability: May 3, 2023

Indication: QALSODY® (tofersen) is indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (*SOD1*) gene. This indication is approved under accelerated approval based on reduction in plasma neurofilament light chain (NfL) observed in patients treated with QALSODY. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

How supplied[1]	100 mg/15 mL (6.7 mg/mL) injection
Packaging[1]	Single-dose vial glass
Carton dimensions	2.28" × 3.15" × 2.56"
Shipping case dimensions	11.25" × 9.5" × 8" or 11.25" × 9.5" × 10.75"
NDC number[1]	64406-109-01
HCPCS Code[2]	J1304 Injection, tofersen, 1 mg
ICD-10-CM Code[3]	G12.21 Amyotrophic lateral sclerosis



Not actual size

HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NDC=National Drug Code.

Dosing: Administer QALSODY intrathecally using a lumbar puncture by, or under the direction of, healthcare professionals experienced in performing lumbar punctures.[1]

The recommended dosage is 100 mg (15 mL) of QALSODY per administration. Initiate QALSODY treatment with three (3) loading doses administered at 14-day intervals. Administer a maintenance dose every 28 days thereafter.[1]

Storage Requirements: Store refrigerated between 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Do not freeze. See product packaging and Prescribing Information for complete list of instructions.[1]

References: 1. QALSODY Prescribing Information. Cambridge, MA: Biogen. **2.** Centers for Medicare & Medicaid Services. January 2024 HCPCS Quarterly Update. Updated December 7, 2023. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update. Accessed April 2, 2024. **3.** 2023 ICD-10-CM Diagnosis Code G12.21. https://www.icd10data.com/ICD10CM/Codes/G00-G99/G10-G14/G12-/G12.21. Accessed April 2, 2024.

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Procuring QALSODY® (tofersen)

Please see Important Safety Information on page 2 and click for full Prescribing Information.

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(tofersen)
100 mg/15 mL injection

QALSODY Is Available Exclusively From Frontier Therapies Through Two Pathways

QALSODY® (tofersen)

SPECIALTY DISTRIBUTOR (SD) – A specialty distributor is a wholesale pharmaceutical distributor that offers special services designed to facilitate drug procurement when products have specialized needs in an effort to ensure supply chain integrity and an optimal patient experience. This form of distribution is common in the rare and/or chronic disease space.

SPECIALTY PHARMACY (SP) – A specialty pharmacy is a licensed pharmacy that offers special services designed to facilitate drug dispensing, reimbursement, and case management for patients with rare and/or chronic diseases and for products that require special handling or may not be widely available at traditional retail pharmacies. They often hold special accreditation related to special services.

Frontier Therapies SD and Frontier Therapies SP are the exclusive providers of QALSODY.

To obtain QALSODY through Frontier Therapies SD, call 1-833-754-6457.

To obtain QALSODY through Frontier Therapies SP, call 1-855-768-9727.

For additional support services for your patients, a Start Form is required. This can be accessed at: QALSODYHCP.com.

Please see Important Safety Information on page 2 and click for full Prescribing Information.

Specialty Distribution (SD) Process

SUBMIT START FORM

- Product Procurement
- Biogen Services Enrollment

BENEFITS & PROCUREMENT VERIFICATION

- Practice or facility verifies benefits and procurement options
- Practice or facility completes PA submission
- Practice or facility confirms payment mechanisms to ensure order can move forward in the process
- FAM/TLL/RDAE is available to answer any reimbursement or procurement questions
- RDRM called when any questions arise from FAM/TLL/RDAE or LCM

ADMINISTRATION SCHEDULED

- Practice or facility schedules administration date and location
- LCM confirms treatment dates with practice or facility

SD ORDER PROCESS

- Practice or facility works directly with Frontier Therapies SD to obtain order form
- Orders must be placed no later than 5 days before scheduled injection. Orders can be sent via fax to 1-866-810-3258, by phone at 1-833-754-6457, or via email at OFT_Wholesale@Optum.com

SHIP

- Frontier Therapies SD prepares, packs, and ships QALSODY via cold-chain pack out to administration site

TREAT

- Practice or facility treats patient
- LCM confirms treatment, as appropriate

START FORM STEPS

- HCP and patient/caregiver complete QALSODY Start Form
- Practice or facility submits QALSODY Start Form to Biogen via fax to 1-888-538-9781 or emails form to StartForm@Biogen.com
- Biogen LCM enrolls patient in Biogen Services

WELCOME

- Biogen LCM initiates welcome call to patient/family
- Biogen LCM confirms accuracy of patient information in system
- Biogen LCM works with the patient, family, and HCP to confirm QALSODY treatment dates, as appropriate

SERVICES

- Insurance and PA investigation is conducted for each patient
- Biogen LCM references information to assist patient/family in navigating logistical, financial, and other nonclinical aspects of QALSODY treatment

Biogen Support Team

FAM - Family Access Manager **LCM** - Lead Case Manager **TLL** - Thought Leader Liaison
RDRM - Rare Disease Reimbursement Manager **RDAE** - Rare Disease Account Executive

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Specialty Pharmacy (SP) Process

SUBMIT START FORM

Product Procurement

Biogen Services Enrollment

SP Rx PROCESS

- Practice or facility verifies benefits and procurement options
- Practice or facility completes PA submission
- As soon as SP procurement has been determined, practice or facility should immediately provide Frontier Therapies SP with Rx
- Preferred and most efficient method is to fax Rx to 1-888-538-9781
- If fax is not an option, then a verbal Rx can be called in to 1-855-768-9727

SP INSURANCE VERIFICATION

- Frontier Therapies SP verifies benefits and identifies patient's health plan requirements
- Practice or facility works with health plan to obtain necessary information (PA and additional documentation)
- Frontier Therapies SP follows up with health plan to obtain insurance approval and may reach out to HCP if additional documentation is required

FINANCIAL ASSISTANCE & SCHEDULING ESTABLISHED

- Frontier Therapies SP works with patient/caregiver and Biogen to determine financial assistance needs
- Site and patient/caregiver schedule appointment

SHIP

- Frontier Therapies SP will process payments*
- Frontier Therapies SP calls practice or facility to confirm shipment date and location with administration site (shipment will not go out until verbal confirmation is made)
- Frontier Therapies SP ships QALSODY via cold-chain pack out to administration site

TREAT

- Practice or facility treats patient
- LCM confirms treatment, as appropriate

START FORM STEPS

- HCP and patient/caregiver complete QALSODY Start Form
- Practice or facility submits QALSODY Start Form to Biogen via fax to 1-888-538-9781 or emails form to StartForm@Biogen.com
- LCM will forward Start Form with initial Rx to Frontier Therapies SP

WELCOME

- Biogen LCM initiates welcome call to patient/family
- Biogen LCM confirms accuracy of patient information in system
- Frontier Therapies SP confirms any necessary information and discusses next steps with HCP/patient
- Biogen LCM works with the patient, family, and HCP to confirm QALSODY treatment dates

SERVICES

- Frontier Therapies SP conducts insurance and PA research for each patient
- Biogen LCM references information to assist patient/family in navigating logistical, financial, and other nonclinical aspects of QALSODY treatment

Biogen Support Team

FAM - Family Access Manager **LCM** - Lead Case Manager **TLL** - Thought Leader Liaison
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*Frontier Therapies SP will bill either pharmacy or major medical benefits depending on plan assignment.
Rx=prescription.

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Relevant Codes

Relevant Codes for QALSODY® (tofersen)

This guide provides an overview of best practices to assist with coding for procedures related to QALSODY administration and ancillary services (if needed).

Always check your patient's plan for coverage and coding guidance

Remember, coding and billing recommendations may vary by payer. Your practice or facility should check directly with the patient's payer(s) for guidance on the appropriate codes to use to facilitate claim processing for QALSODY, its administration, and any ancillary services. Biogen field representatives are available to answer questions and further support the reimbursement process.

Summary of Relevant Codes for QALSODY® (tofersen)

ICD-10-CM CODE EXAMPLES

ICD-10-CM Code[1]	Description[1]
G12.21	Amyotrophic lateral sclerosis

HCPCS CODE

HCPCS Code[2]	Description[2]
J1304	Injection, tofersen, 1 mg

MODIFIERS

Modifier[3,4]	Description[3,4]
JZ	Indicates zero drug wasted/not administered to any patient
JG	340B-acquired drug
TB*	340B drug: select entities

NDC NUMBER

NDC Number[5]		Description[5]
10-digit format	11-digit format	
64406-109-01	64406-0109-01	100 mg/15 mL single-dose vial (contains 100 mg of tofersen solution for intrathecal injection)

*The **340B Program** allows certain hospitals to buy outpatient drugs at discounted prices. Beginning no later than **January 1, 2025**, if you're a 340B-covered entity, you must report the "TB" modifier on claims, even if you're using the "JG" modifier.

References: 1. 2023 ICD-10-CM Diagnosis Code G12.21. https://www.icd10data.com/ICD10CM/Codes/G00-G99/G10-G14/G12-/G12.2. Accessed April 2, 2024. **2.** Centers for Medicare & Medicaid Services. January 2024 HCPCS Quarterly Update. Updated December 7, 2023. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update. Accessed April 2, 2024. **3.** Centers for Medicare & Medicaid Services. Billing and Coding: JW and JZ Modifier Billing Guidelines. Updated January 10, 2023. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55932. Accessed April 2, 2024. **4.** Centers for Medicare & Medicaid Services. Billing 340B Modifiers under the Hospital Outpatients Prospective Payment System (OPPS). March 3, 2024. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/billing-340b-modifiers-under-hospital-opps.pdf. Accessed April 2, 2024. **5.** QALSODY Prescribing Information. Cambridge, MA: Biogen.

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Summary of Relevant Codes for QALSODY® (tofersen) (cont'd)

CPT® CODE EXAMPLES

Procedure Type	CPT® Code	Description
Drug Administration & Surgical Procedure	96450	Chemotherapy administration, into CNS (eg, intrathecal), requiring and including spinal puncture
	62272	Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter)
	62329	Spinal puncture, therapeutic, for draining of cerebrospinal fluid (by needle or catheter) with fluoroscopic or CT guidance
Imaging Procedure/ Guidance	77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid)
	76942	Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation
	77012	CT guidance for needle placement (eg, biopsy, aspiration, injection, localization device), radiological supervision and interpretation
Observation or Inpatient Care Services	99234	Observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date. Usually the presenting problem(s) requiring admission are of low severity and typically 40 minutes are spent at the bedside and on the patient's hospital floor or unit.
	99235	Observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date. Usually the presenting problem(s) requiring admission are of moderate severity and typically 50 minutes are spent at the bedside and on the patient's hospital floor or unit.
	99236	Observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date. Usually the presenting problem(s) requiring admission are of high severity and typically 55 minutes are spent at the bedside and on the patient's hospital floor or unit.

CNS=central nervous system; CPT=Current Procedural Terminology; CT=computed tomography.

Reference: American Medical Association. *CPT® 2021 Professional Edition*. 2020.

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Coverage Processes

QALSODY® (tofersen) Benefits Investigation Guide

A Benefits Investigation is a process that enables a practice or facility to determine benefit design, coverage requirements, coding guidance, and drug acquisition options for a specific patient before administering treatment. For QALSODY, your practice or facility will need to know how the patient's health plan covers both the drug component and the administration component. Note that QALSODY will most often be covered under the health plan's medical benefit.

It is important to determine your patient's level of coverage before each administration of QALSODY because health plan coverage can vary and change over time.

Suggested practices for conducting a benefits investigation/verification:

- Establish universal guidelines and identify common resources to help standardize the benefits investigation/verification process
- Prior to initiating a benefits verification, confirm that the patient's health plan information is accurate and up to date
- If the patient has coverage from more than 1 health plan, confirm coordination of benefits between primary and secondary payers. All patients with ALS qualify for Medicare after receiving Social Security Disability Insurance (SSDI). If dual-eligible, Medicare must be billed first
- Communicate patient's benefits or provide a summary of benefits to the appropriate members of the patient's care team
- Determine key elements of the health plan's cost-sharing structure
- Identify and record any payer-specific requirements for PA and/or sites of care (eg, in-network, treatment in same state policy was issued)
- Establish a plan and frequency to verify the patient's benefits at regular intervals (eg, prior to ordering the next dose of QALSODY)

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PA Submission Guide for QALSODY® (tofersen)

Steps and Best Practices to Completing a PA

PAs are very common for orphan drugs that treat rare diseases, such as QALSODY, because they enable health plans to monitor costs and ensure that drugs are being used for appropriate patients only. Dedicating staff to manage/oversee the authorization process can reduce administrative denials.

Steps to Completing a PA if Required Following a Benefits Investigation:

Step 1: Complete and submit the PA request

- Identify, review, and document any payer-specific requirements for authorization requests
- Fill out the appropriate PA form for that health plan and include supplemental documents to strengthen the request
  - Most PAs for QALSODY include: a genetic test, baseline physical therapy evaluation, clinical notes, and a letter of medical necessity
- Be sure to communicate with a patient navigator who oversees the logistics of coordinating each patient treatment throughout the facility

Step 2: Track the status of the request

- Maintain a thorough log of the PA submissions and denials for each patient, as this information will be needed if the patient wishes to apply for financial support services

Step 3: Follow up as needed

- If additional documentation is requested at any point, make sure to provide it as soon as possible
- If authorization is granted, document any payer or plan-specific requirements outlined in the authorization or plan policy, including, but not limited to:
  - Duration of authorization and requirements/timing for authorization renewal

One of the main reasons PA requests are denied is incomplete or inaccurate information on the PA form. Dedicating staff to manage/oversee the authorization process can reduce administrative denials.

Please see Important Safety Information on page 2 and click for full Prescribing Information.

Medical Exceptions Guide for QALSODY® (tofersen)

Steps and Best Practices for Requesting a Medical Exception (ME)

An ME communicates a physician's request to use a medication (citing the patient's individual circumstances) that is nonpreferred or not covered by the patient's health plan.

Step 1: Complete the ME request with a letter of medical necessity for QALSODY, as needed

- Find out if the health plan has its own ME request form or will accept a separate letter from your office

Step 2: Submit and track your ME request

- Submit the ME via phone, fax, email, or the company's website. Then, identify the appropriate individual to contact regarding the progress of the ME request

Suggested practices

Provide background on your patient's condition:

- Summarize his or her clinical status citing diagnostic evidence of ALS
- If appropriate, list current supportive care management and provide clinical evidence of the patient's disease progression despite supportive care

Why QALSODY is, in your opinion, the appropriate treatment choice for your patient:

- Provide a clinical justification supporting QALSODY treatment for your patient and cite any relevant literature
- State any patient-specific reasons for the treatment choice
- Review the health plan's medical policy criteria and point out the criteria that your patient meets. Explain why your patient should be excluded from any criteria that he or she does not meet, as appropriate

Providing additional documentation that supports your decision may strengthen your request:

- General medical history listing comorbidities and any medication history, if appropriate
- Letters from other healthcare professionals (such as physical therapists or nurses) that support your treatment choice
- Clinical information regarding your treatment choice

A common reason that MEs are denied is that information is missing from or incorrect on the form. This may delay treatment for your patient. Remember to carefully and accurately complete the ME request form.

Please see Important Safety Information on page 2 and click for full Prescribing Information.

Appeals Guide for QALSODY® (tofersen)

Steps for Appealing a Denial

Sometimes, even if treatment with QALSODY is medically necessary, coverage may still be denied. An appeal is a request to your patient's health plan to reverse its decision and approve QALSODY.

Step 1: Understand the reason for the denial

- Identify the reason that treatment was denied and contact the health plan to find a way to resolve the matter

Step 2: Appeal the denial

- Complete the health plan's appeal request form and follow important guidelines and timeframes
- Refer to the **Sample Letter of Medical Necessity/Appeal for QALSODY, available at** QALSODYhcp.com, for support and for information you may want to include with your appeal request

Step 3: Monitor the appeal

- Follow up with the health plan to confirm that your request was received and to check the status of its decision
- Notify the patient of instances for which your office may need his or her involvement

There are often multiple levels of appeal depending on the health plan. Please be sure to connect with the health plan directly to discuss all options for appeal.

If the appeal is denied

- For Medicare patients, a denied appeal will automatically be sent to an external review. For non-Medicare patients, a request may be required
- Your patient can ask for an external review (by an independent, accredited medical professional) or a peer review. This is helpful for patients with ALS because it means their health plans will no longer have the final say regarding their coverage
- If all attempts at coverage are denied by the primary health plan, you may appeal to a secondary health plan

Affordability

Financial Assistance Options for QALSODY® (tofersen)

The Biogen Copay Program offers 2 ways in which your patients may be eligible for financial assistance for QALSODY itself and for some of the treatment costs.

Please note that these are 2 different programs, and your patients must enroll separately as needed.

1 Copay Assistance Program

- Most individuals on non-government insurance are eligible, regardless of income. This copay assistance is limited to an annual cap, which is based on certain factors, including but not limited to, insurance coverage, claims details, and/or participation in other plan-sponsored programs
- Insurance will be billed first and must pay before copay assistance will be applicable
- Individuals receiving coverage from Medicare, Medicaid, Veterans Affairs/Department of Defense (DoD), TRICARE®*, or any other governmental or pharmaceutical assistance may not be eligible

2 Administration Copay Assistance Program

In addition to the above criteria, individuals are eligible for this program if they meet the following requirements:

- They are not a resident of Massachusetts, Michigan, Minnesota, or Rhode Island
- The HCP submits a request for treatment using an approved procedure code. The program does not cover lab work, observation, surgical supplies, facility/room costs, or other miscellaneous costs that may be associated with the administration of QALSODY

Your FAM is available to assist your patients with enrollment in the **Biogen Copay Program** or any questions regarding financial assistance. The QALSODY Copay Reimbursement Form, which is used for both copay programs, is also available at **QALSODY.com**.

Please see Important Safety Information on page 2 and click for full Prescribing Information.

Financial Assistance Options for QALSODY® (tofersen) (cont'd)

Biogen Support Services for Your Patients

Biogen Support Services is a support program that provides a variety of financial and insurance assistance options. These resources can help your patients start and continue on QALSODY.

Our Support Coordinators are committed to:

Answering general disease and product questions, as well as questions about Biogen Support Services

Assisting with access to treatment and removal of nonclinical barriers

BIOGEN SUPPORT SERVICES FOR PATIENTS

Call **1-877-725-7639**
Monday–Friday, 8:30 AM to 8:00 PM ET

Medicare Eligibility for Patients With ALS

Patients who have been diagnosed with ALS and are approved for SSDI automatically qualify for Medicare.[1] To sign up for Medicare, patients must first qualify for SSDI and receive benefits. Patients with ALS are exempt from the 24-month waiting period and will immediately receive Medicare coverage as soon as they receive SSDI benefits.

To learn more about disability benefits offered through Social Security, call **1-800-772-1213** or visit **https://www.ssa.gov/benefits/disability**.

Reference: 1. ALS Association. Signing Up for Medicare. https://www.als.org/navigating-als/financial-information/signing-up-for-medicare. Accessed February 27, 2024.

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