IPSENCARES®
Coverage, Access, Reimbursement & Education Support

Bylvay® (odevixibat)
200 | 400 | 600 | 1200 mcg capsules

Guide to Writing a Supporting Statement for a Medicare Part D Exception Request

A supporting statement for a Medicare Part D exception request explains the prescriber's rationale and clinical decision-making for choosing a specific treatment option.

There are 2 types of exception requests[1]:

Tier exception

A request to obtain a non-preferred drug at a lower cost-sharing level

Formulary exception

A request to obtain a non-formulary drug or to have a utilization management requirement waived (eg, step therapy, prior authorization)

Use of this information does not guarantee that a health plan will provide coverage for Bylvay and is not intended to be a substitute for, or to influence, your independent medical judgment.

The following pages share tips for writing an effective supporting statement and provide a template you can use to write your statement for individual patients.

Call 1-866-435-5677, Monday - Friday, 8:00 AM - 8:00 PM ET, for additional information, or visit us online at IPSENCARES.com

Reference: 1. Exceptions. Centers for Medicare & Medicaid Services. Updated September 10, 2024. Accessed July 3, 2025. https://www.cms.gov/medicare/appeals-grievances/prescription-drug/exceptions

Tips for Writing an Effective Supporting Statement for Medicare Part D Patients

Before you begin writing a supporting statement for a Medicare Part D Exception Request, have the following information ready:

- Patient's full name and date of birth
- Patient's insurance policy/ID number
- Case ID number (for appeals)
- Brief medical history, including diagnosis, ICD-10 code, comorbidities, and allergies
- Patient's current and prior therapeutic regimens (include start/stop dates and the reason[s] for discontinuation)
- Background on the patient's current condition and symptoms
- Clinical support for your recommendation

Consider these additional points when writing your supporting statement for Bylvay:

- **Review the health plan's coverage criteria** for Bylvay and provide details on the criteria that your patient meets. If applicable, provide your rationale for excluding your patient from criteria they do not meet
- **Clearly state** why Bylvay is medically necessary for the patient and that the preferred drug(s) (for **tier exceptions**) or covered option(s) (for **formulary exceptions**) would not be as effective and/or would have adverse effects[1]
- **Provide clinical justification** to support your decision to prescribe Bylvay, and attach relevant clinical data such as chart notes and laboratory test results and pregnancy status[2]
- **Describe** any other patient characteristics and/or clinical considerations relevant to Bylvay therapy
  - Attach clinical documentation that supports your recommendation[2]

Be mindful of following preferred health plan processes:

- Read the process for submitting the letter to ensure that you are meeting the requirements of the health plan and state guidelines, including how to submit the request (eg, fax, phone, email, health plan website)
- Track the status of your request and follow up with the health plan if needed

IPSEN CARES can help provide logistical information about submitting letters

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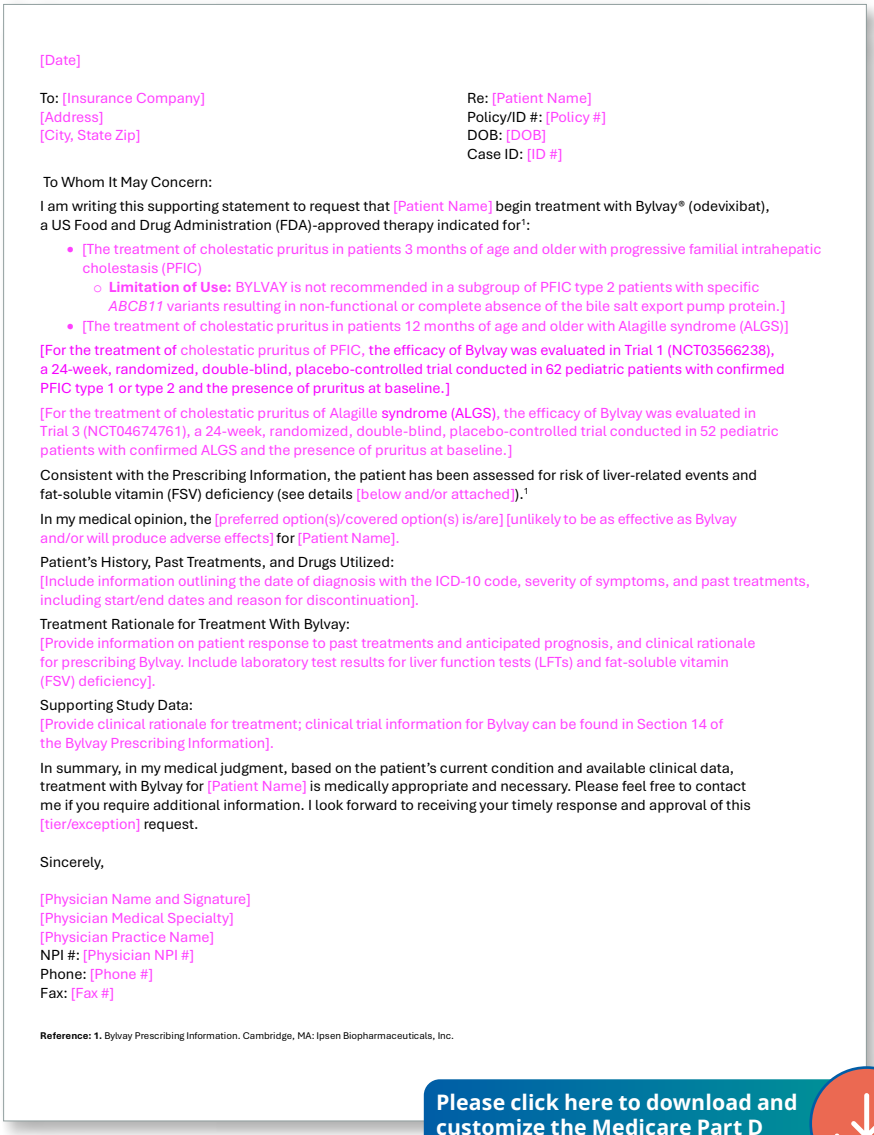
ICD-10, International Classification of Diseases, Tenth Revision.

References: 1. Exceptions. Centers for Medicare & Medicaid Services. Updated September 10, 2024. Accessed July, 2025. https://www.cms.gov/medicare/appeals-grievances/prescription-drug/exceptions **2.** Bylvay Prescribing Information. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.

Sample Medicare Part D Supporting Statement for Bylvay

The image below shows the format for a sample supporting statement for Bylvay that uses a downloadable template. Take a look to get a sense of what a statement format may look like and then you may download the template to customize it based on your medical opinion and your individual patient's needs.



[Date]

To: [Insurance Company]
[Address]
[City, State Zip]

Re: [Patient Name]
Policy/ID #: [Policy #]
DOB: [DOB]
Case ID: [ID #]

To Whom It May Concern:

I am writing this supporting statement to request that [Patient Name] begin treatment with Bylvay® (odevixibat), a US Food and Drug Administration (FDA)-approved therapy indicated for[1]:

- [The treatment of cholestatic pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC)
  - **Limitation of Use:** BYLVAY is not recommended in a subgroup of PFIC type 2 patients with specific *ABCB11* variants resulting in non-functional or complete absence of the bile salt export pump protein.]
- [The treatment of cholestatic pruritus in patients 12 months of age and older with Alagille syndrome (ALGS)]

[For the treatment of cholestatic pruritus of PFIC, the efficacy of Bylvay was evaluated in Trial 1 (NCT03566238), a 24-week, randomized, double-blind, placebo-controlled trial conducted in 62 pediatric patients with confirmed PFIC type 1 or type 2 and the presence of pruritus at baseline.]

[For the treatment of cholestatic pruritus of Alagille syndrome (ALGS), the efficacy of Bylvay was evaluated in Trial 3 (NCT04674761), a 24-week, randomized, double-blind, placebo-controlled trial conducted in 52 pediatric patients with confirmed ALGS and the presence of pruritus at baseline.]

Consistent with the Prescribing Information, the patient has been assessed for risk of liver-related events and fat-soluble vitamin (FSV) deficiency (see details [below and/or attached]).[1]

In my medical opinion, the [preferred option(s)/covered option(s) is/are] [unlikely to be as effective as Bylvay and/or will produce adverse effects] for [Patient Name].

Patient's History, Past Treatments, and Drugs Utilized:
[Include information outlining the date of diagnosis with the ICD-10 code, severity of symptoms, and past treatments, including start/end dates and reason for discontinuation].

Treatment Rationale for Treatment With Bylvay:
[Provide information on patient response to past treatments and anticipated prognosis, and clinical rationale for prescribing Bylvay. Include laboratory test results for liver function tests (LFTs) and fat-soluble vitamin (FSV) deficiency].

Supporting Study Data:
[Provide clinical rationale for treatment; clinical trial information for Bylvay can be found in Section 14 of the Bylvay Prescribing Information].

In summary, in my medical judgment, based on the patient's current condition and available clinical data, treatment with Bylvay for [Patient Name] is medically appropriate and necessary. Please feel free to contact me if you require additional information. I look forward to receiving your timely response and approval of this [tier/exception] request.

Sincerely,

[Physician Name and Signature]
[Physician Medical Specialty]
[Physician Practice Name]
NPI #: [Physician NPI #]
Phone: [Phone #]
Fax: [Fax #]

Reference: 1. Bylvay Prescribing Information. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.

Please click here to download and customize the Medicare Part D Exception Request

This template is for informational purposes only, providing an outline of the types of information that may be required or helpful when responding to a request from a patient's health plan. Use of this information does not constitute medical or legal advice and does not guarantee reimbursement for coverage. It is not intended to be a substitute for, or an influence on, the independent clinical decision of the prescribing healthcare professional. IPSEN makes no representations or warranties about the template or its fitness for any specific use. IPSEN is not responsible for any changes made to the template document. All billing and coding decisions are the responsibility of the relevant physician.

Indication and Important Safety Information for Bylvay

INDICATIONS

BYLVAY is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of:

- cholestatic pruritus in patients ≥12 months of age with Alagille syndrome (ALGS)
- pruritus in patients ≥3 months of age with progressive familial intrahepatic cholestasis (PFIC)

Limitation of Use:

BYLVAY is not recommended in a subgroup of PFIC type 2 patients with specific *ABCB11* variants resulting in non-functional or complete absence of the bile salt export pump protein.

IMPORTANT SAFETY INFORMATION

Contraindications

IBAT inhibitors, including BYLVAY, are contraindicated in patients with prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy).

WARNINGS AND PRECAUTIONS

Hepatotoxicity

BYLVAY treatment is associated with a potential for drug-induced liver injury (DILI). In the PFIC and ALGS trials, treatment-emergent elevations or worsening of liver tests occurred. Of the six patients who experienced DILI, two underwent liver transplant.

Obtain baseline liver tests because some ALGS and PFIC patients have abnormal liver tests at baseline and monitor patients frequently for the first 6 to 8 months, and as clinically needed thereafter, for elevations in liver tests, for the development of liver-related adverse reactions, and for physical signs of hepatic decompensation. If liver test abnormalities or signs of clinical hepatitis occur in the absence of other causes, consider dose reduction or treatment interruption. Permanently discontinue BYLVAY if a patient experiences the following: persistent or recurrent liver test abnormalities, or upon rechallenge, signs and symptoms consistent with clinical hepatitis, or a hepatic decompensation event.

The safety and effectiveness of BYLVAY have not been established in patients with decompensated cirrhosis. Monitor patients with compensated cirrhosis or portal hypertension more frequently and discontinue if hepatic decompensation occurs. IBAT inhibitors, including BYLVAY, are contraindicated in patients with prior or active hepatic decompensation events.

Diarrhea

In the PFIC and ALGS clinical trials, diarrhea was reported more frequently in BYLVAY-treated patients compared to placebo. In the PFIC clinical trials, treatment interruption due to diarrhea occurred in 2 patients with 3 events.

Treatment interruption due to diarrhea ranged between 3 to 7 days. One patient withdrew from the trial. In the ALGS clinical trial, no patients interrupted or discontinued treatment due to diarrhea.

If diarrhea occurs, monitor for dehydration and treat promptly. Interrupt dosing if a patient experiences persistent diarrhea. Restart BYLVAY at 40 mcg/kg/day when diarrhea resolves and increase the dose as tolerated if appropriate. If diarrhea persists and no alternate etiology is identified, stop treatment.

Indication and Important Safety Information for Bylvay (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Fat-Soluble Vitamin (FSV) Deficiency

Fat-soluble vitamins (FSV) include vitamin A, D, E, and K. PFIC and ALGS patients can have FSV deficiency at baseline. BYLVAY may adversely affect absorption of FSVs. In clinical trials, new onset or worsening of existing FSV deficiency was reported more frequently in BYLVAY-treated patients compared to placebo.

Obtain baseline INR (International Normalized Ratio) and FSV levels and monitor during treatment along with any clinical manifestations. If FSV deficiency is diagnosed, supplement with FSV. Discontinue BYLVAY if FSV deficiency persists, worsens, or complications occur despite adequate FSV supplementation.

If bone fracture occurs, consider interrupting BYLVAY treatment and supplement with FSV if indicated.

If bleeding occurs, interrupt treatment with BYLVAY. Optimize treatment of FSV deficiency and consider restarting BYLVAY once the patient is clinically stable.

Adverse Reactions

The most common adverse reactions for BYLVAY in patients with PFIC are diarrhea, liver test abnormalities, vomiting, abdominal pain, and FSV deficiency.

The most common adverse reactions for BYLVAY patients with ALGS are diarrhea, abdominal pain, hematoma, and decreased weight.

Drug Interactions

For patients taking bile acid binding resins, take BYLVAY at least 4 hours before or 4 hours after taking a bile acid binding resin.

Use in Specific Populations

Limited human data on BYLVAY use in pregnant persons are insufficient to establish a drug-associated risk of major birth defects, miscarriage, or adverse developmental outcomes. Based on findings from animal reproduction studies, BYLVAY may cause cardiac malformations when a fetus is exposed during pregnancy. As BYLVAY may inhibit the absorption of fat-soluble vitamins, which are essential for normal fetal growth and development, monitor pregnant patients for FSV deficiency and increase supplementation as needed. Consider the woman's need for BYLVAY, the potential drug-related risks to the fetus, and the potential adverse outcomes from untreated maternal PFIC and ALGS.

There is a pregnancy exposure registry that monitors pregnancy outcomes in persons exposed to BYLVAY during pregnancy. Pregnant women exposed to BYLVAY, or their healthcare providers, should report BYLVAY exposure by calling 1-855-463-5127.

To report SUSPECTED ADVERSE REACTIONS, contact Ipsen Biopharmaceuticals, Inc. at 1-855-463- 5127 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information.

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