For pruritus in your adult patients with progressive familial intrahepatic cholestasis (PFIC)

Take on the day with once-daily BYLVAY®[1]

RAPID REDUCTIONS IN PRURITUS

AS EARLY AS WEEKS 1-4[1,2]

PEDFIC 1 Key Efficacy Endpoint:
Mean percentage of pruritus assessments scored as little to no scratching (BYLVAY 40 mcg/kg/day 35%, BYLVAY 120 mcg/kg/day 30% vs placebo 13%)[1]

PEDFIC 1 Primary Endpoint:
Proportion of positive pruritus assessments over 24 weeks (All BYLVAY 55% vs placebo 30%)[3]

The mean of patients' worst weekly average scratching scores in each treatment group for each month, where the weekly average utilized the worst score from each day (morning or evening score), was assessed in PEDFIC 1.[1]

All images are actor portrayals.

INDICATION

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

Please see additional Important Safety Information throughout, and the full Prescribing Information.

These familiar patient presentations may disguise PFIC[4-15]

Certain patient presentations of progressive cholestasis should be assessed for a PFIC diagnosis

Idiopathic or cryptogenic cholestasis
- Signs of cholestasis without apparent cause[4,5]
- Medical and familial history[6]

Cholestasis with pruritus or unusual presentation
- Small duct PSC[4,7-9]
- AMA negative PBC[8,9]
- MASLD* with pruritus[10]
- Lean MASLD* without metabolic syndrome[10]
- Lean MASH* with pruritus and without metabolic syndrome[10]

Secondary cholestasis triggered by liver issue
- All women with a history of ICP[4,7]
- Drug-induced cholestasis[4,7]
- Hormone-induced cholestasis triggered by birth control, menopause, anabolic steroids, augmentin/certain antibiotics, etc[7,11,12]

History of complicated gallstones
- Hepatolithiasis[7,9]
- Very strong family history of gallstones or incident at a young age[4,13,14]
- LPAC leading to stones in the gallbladder or liver[4,15]

PFIC is a rare disease, and symptoms overlap with other hepatic conditions, increasing the risk of misdiagnosis[16]

*A multisociety Delphi consensus proposed a change to steatotic liver disease nomenclature, with metabolic dysfunction-associated steatotic liver disease (MASLD) chosen to replace NAFLD, and metabolic dysfunction-associated steatohepatitis (MASH) chosen to replace NASH.[17]

AMA=antimitochondrial antibody; GGT=gamma-glutamyl transferase; ICP=intrahepatic cholestasis of pregnancy; LPAC=low phospholipid-associated cholelithiasis; NAFLD=nonalcoholic fatty liver disease; NASH=nonalcoholic steatohepatitis; PBC=primary biliary cholangitis; PSC=primary sclerosing cholangitis.

PFIC can affect adults[18-20]

While previously thought to be a pediatric condition, it is now clear that PFIC can have adult onset[18-20]

PFIC means progressive familial intrahepatic cholestasis[20,21]
- A group of rare genetic liver disorders[20,21]
- A result of genetic variants involving[20,21] the formation or transport of bile[20,21]

Clinical presentation can be highly variable[20]
- May be episodic or insidious[16,19,20,22]
- May present later in life after a specific trigger[16,20]

Could PFIC be hiding in your practice?
- A large cohort of 356 patients with adult-onset liver disease were screened for suspected genetic contribution[19]
- **28% had ≥1 potentially pathogenic variant in PFIC-causing genes** *ABCB4, ABCB11,* or *ATP8B1*[19]

While PFIC commonly presents in the first months of life, it is now evident that variants in PFIC-associated genes *ABCB4*, *ABCB11*, and *ATP8B1* can contribute to later onset forms of the disease[19]

Be confident in your adult PFIC diagnosis

The hallmark signs and symptoms of adult PFIC include[20]:

- Pruritus
- High serum bile acid (sBA) levels
- Jaundice with or without elevated GGT

Could it be PFIC?

- Cholestatic pruritus following recent liver issue[4,23]
- History of complicated gallstones/LPAC[4,23]
- Family history of liver disease/liver issue[23]

If no likely cause is identified, continue reassessing

Making a diagnosis

Tests and procedures that may help establish a diagnosis include[18,24]:

- Biochemical tests (elevated sBA, elevated ALP, normal or elevated GGT, AMA and ANA levels)
- Additional imaging (ultrasound, MRCP, fibroscan)
- Supportive genetic analysis (*ATP8B1*, *ABCB11*, *ABCB4*, and other PFIC-associated genes)

An evaluation that uses a combined approach of clinical, imaging, and biochemical assessments is sufficient to support a PFIC diagnosis and initiate treatment[6,25]

Please see additional Important Safety Information throughout, and the full Prescribing Information.

BYLVAY is the first FDA-approved IBAT inhibitor for the treatment of pruritus in PFIC[1,26]

BYLVAY inhibits the reabsorption of bile acids[1]

BYLVAY is a reversible IBAT inhibitor that disrupts a key aspect of enterohepatic circulation to reduce bile acid reuptake, seen through lower serum bile acid levels[1,27]

BYLVAY delivered reductions in pruritus through Week 24[1-3]

PEDFIC 1 Key Efficacy Endpoint: Mean percentage of pruritus assessments scored as little to no scratching (BYLVAY 40 mcg/kg/day 35%, BYLVAY 120 mcg/kg/day 30% vs placebo 13%)[1]

Safety profile established through 96 weeks of clinical trial data[3,28]

BYLVAY offers once-daily oral dosing with flexible administration options[1]

BYLVAY can be taken 3 ways: capsules can be swallowed whole, or opened and mixed with soft food or liquids[1*]

Approved to treat pruritus in all PFIC types including newly detected subtypes[1]

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.[1]

*Add 1 teaspoon (5 mL) of liquid. After mixing BYLVAY with food or liquids, discard the empty shells.[1]

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS

Hepatotoxicity

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

PEDFIC 1 is the **FIRST COMPLETED GLOBAL** Phase 3 clinical trial in PFIC[3,29]

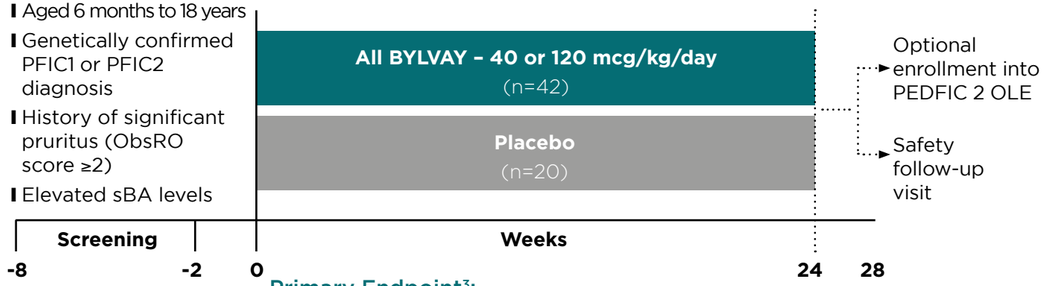
PEDFIC 1[3]

24-week randomized, double-blind Phase 3 study[3]

All BYLVAY doses were administered once daily

Enrolled participants[3]:

- Aged 6 months to 18 years
- Genetically confirmed PFIC1 or PFIC2 diagnosis
- History of significant pruritus (ObsRO score ≥2)
- Elevated sBA levels



Primary Endpoint[3]:

- Proportion of participant's positive pruritus assessments over 24 weeks*

Secondary Endpoints included[3]:

- Proportion of participants with sBA response at Week 24†
- Change in sleep parameters through Week 24‡

Concomitant ursodeoxycholic acid (UDCA) and other antipruritic medications were permitted provided they were at a stable dose at least 4 weeks before enrollment with no dosage changes planned during the study period.[3]

89% of participants were receiving UDCA or rifampicin at PEDFIC 1 baseline.[30]

*Defined as a scratching score of ≤1 or at least a 1-point reduction from baseline on the PRUCISION™ ObsRO instrument.[3]
†sBA response was defined as at least a 70% decrease in sBA or a final sBA level of ≤70 µmol/L.[3]
‡Data reported using the PRUCISION™ ObsRO instrument; caregivers answered up to 9 questions about the effects that itch had on the participant's sleep and sleep-related parameters daily.[30]
ObsRO=observer-reported outcome; sBA=serum bile acids.

Cholestatic pruritus was measured using the PRUCISION™ ObsRO scale[3]

PRUCISION™ ObsRO Scale[31]

A **validated** instrument that defines a ≥1-point reduction as a clinically meaningful change in pruritus score.[3,31]

Scratching scores were recorded twice daily by an observer[3,31]:

- AM score recorded worst scratching since going to bed the previous night
- PM score recorded worst scratching since waking up

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS

Hepatotoxicity (cont'd)

Obtain baseline liver tests because some 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.

Please see additional Important Safety Information throughout, and the full Prescribing Information.

Rapid and durable reduction in pruritus as early as Weeks 1-4[1-3]

RAPID ITCH REDUCTION

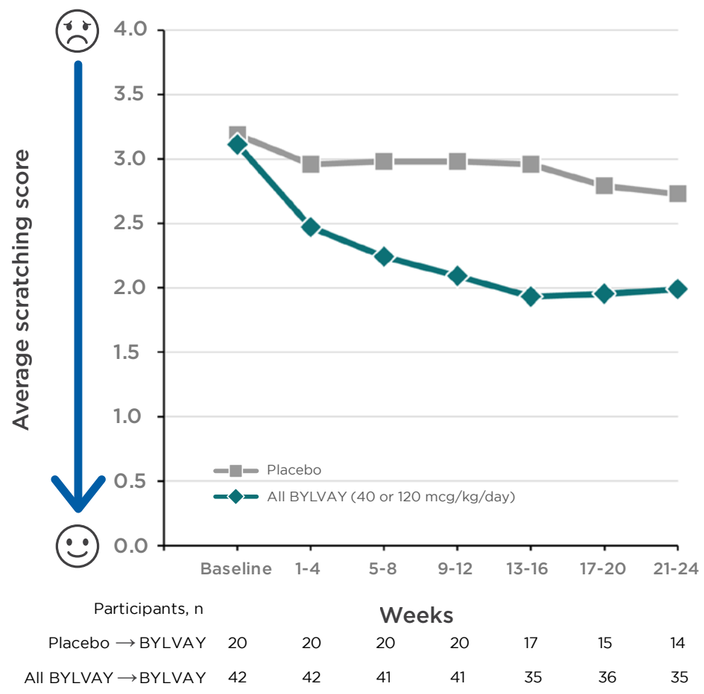
Pruritus reduction data at Weeks 1-4[33]

Little to no scratching achieved with BYLVAY[1]

Key Efficacy Endpoint: Proportion of pruritus assessments achieving little or no scratching (score ≤1) through Week 24[1]*

35%	**30%**	vs **13%**
on BYLVAY 40 mcg/kg/day (n=23)	on BYLVAY 120 mcg/kg/day (n=19)	with placebo (n=20)

PEDFIC 1: Worst average scratching score through Week 24[1,3]



Participants, n							
Placebo → BYLVAY	20	20	20	20	17	15	14
All BYLVAY → BYLVAY	42	42	41	41	35	36	35

47% of participants treated with BYLVAY experienced a clinically meaningful improvement† through Week 24[32]

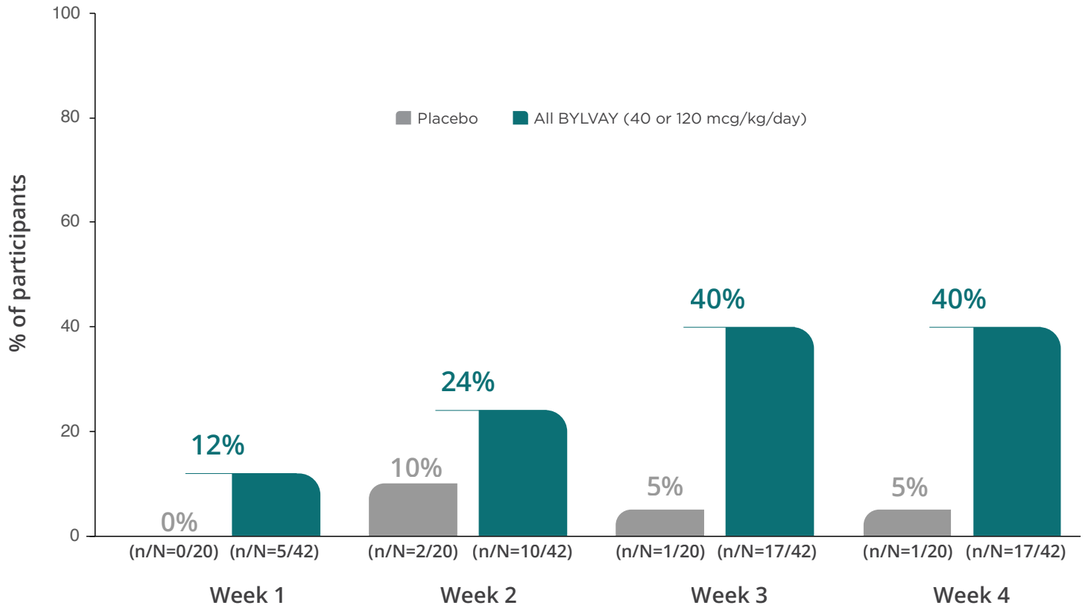
*Mean difference vs placebo (95% CI): BYLVAY 40 mcg/kg/day: 22.2 (4.7, 39.6); BYLVAY 120 mcg/kg/day: 16.9 (-2.0, 35.7). N=62.[1]

†Defined as a ≥1-point improvement in ObsRO score.[3]

ObsRO=observer-reported outcome; OLE=open-label extension; sBA=serum bile acid.

Please see additional Important Safety Information throughout, and the full Prescribing Information.

Proportion of participants experiencing a clinically meaningful* reduction in average scratching score at Weeks 1 to 4[33]



LIMITATION: Data are descriptive and not powered to determine statistical significance; interpret with caution.

*Defined as a ≥1-point reduction in ObsRO score.[3]

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS

Hepatotoxicity (cont'd)

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.

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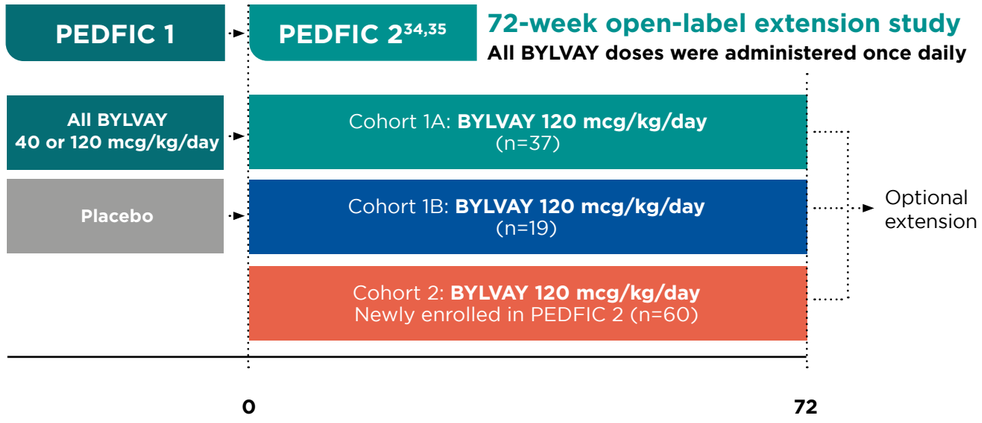
PEDFIC 2 is an open-label extension study to assess long-term efficacy and safety[34]



Eligibility criteria[34]:

- Any age
- Any PFIC type
- History of significant pruritus
- Elevated sBA levels

Primary Endpoint[34]:

- Proportion of participant's positive pruritus assessments over 72 weeks*

Secondary Endpoints included[34]:

- Change from baseline in sBA at Week 72

Exploratory Endpoint[34]:

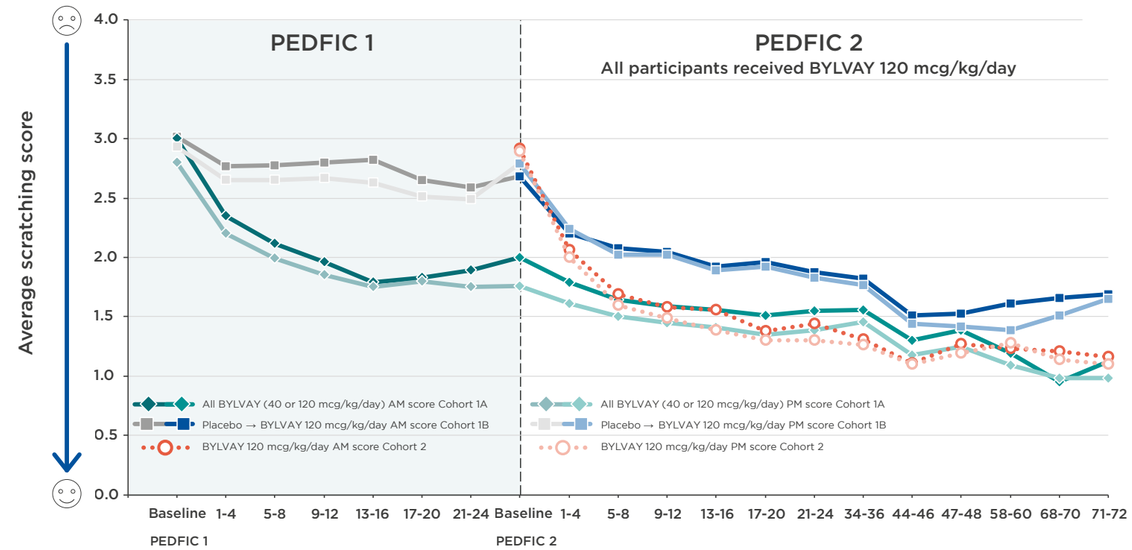
- Change in sleep parameters through Week 72†

*Defined as a scratching score of ≤1 or at least a 1-point reduction from baseline on the PRUCISION™ ObsRO instrument.[34]

†Data reported using the PRUCISION™ ObsRO instrument; caregivers answered up to 9 questions about the effects that itch had on the participant's sleep and sleep-related parameters daily.[34,35]

ObsRO=observer-reported outcomes; OLE=open-label extension; sBA=serum bile acid.

Average day and night scratching scores through Week 96[36]*



Participants, n (AM / PM)	Baseline	1-4	5-8	9-12	13-16	17-20	21-24	Baseline	1-4	5-8	9-12	13-16	17-20	21-24	34-36	44-46	47-48	58-60	68-70	71-72
Placebo → BYLVAY	20/20	20/20	20/20	20/20	17/17	15/15	14/14	19/19	19/19	19/19	19/19	18/18	18/18	17/17	16/16	14/14	14/14	13/13	13/13	12/12
All BYLVAY → BYLVAY	42/42	42/42	41/41	41/41	35/35	36/36	35/35	36/37	37/37	37/37	37/37	37/37	36/37	36/36	30/31	28/28	29/29	31/31	22/21	28/26
BYLVAY Cohort 2	—	—	—	—	—	—	—	53/53	53/53	51/51	49/50	48/50	47/48	45/46	43/43	36/37	41/41	33/33	28/28	30/32

LIMITATION: Data are descriptive and not powered to determine statistical significance; interpret with caution.

Reductions were observed through Week 96[36]

PEDFIC 2 is an open-label extension of the PEDFIC 1 trial.[34]

*AM score reflects nighttime scratching; PM score reflects daytime scratching.[37]

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS

Hepatotoxicity (cont'd)

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.

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Through Week 24
Safety profile established in PEDFIC 1[3]

PEDFIC 1: Serious TEAEs[3]

Placebo (n=20) n (%)	BYLVAY 40 mcg/kg/day (n=23) n (%)	BYLVAY 120 mcg/kg/day (n=19) n (%)
5 (25)	0	3 (16)

- All SAEs were unrelated to treatment, and none led to discontinuation[38]
  - Treatment-emergent SAEs in the BYLVAY 120 mcg/kg/day group included supraventricular tachycardia, urinary tract infection, dehydration, and elevated liver function tests
- No deaths were reported[3]

PEDFIC 1: Common Adverse Reactions (≥2%)[1]

Adverse reaction	Placebo (n=20) n (%)	BYLVAY 40 mcg/kg/day (n=23) n (%)	BYLVAY 120 mcg/kg/day (n=19) n (%)
Diarrhea	2 (10)	9 (39)	4 (21)
Transaminases increased (ALT, AST)	1 (5)	3 (13)	4 (21)
Vomiting	0	4 (17)	3 (16)
Abdominal pain	0	3 (13)	3 (16)
Blood bilirubin increased	2 (10)	3 (13)	2 (11)
Fat-soluble vitamin deficiency (A, D, E)	1 (5)	0	3 (16)
Splenomegaly	0	0	2 (11)
Cholelithiasis	0	0	1 (5)
Dehydration	0	0	1 (5)
Fracture	0	1 (4)	0

- Most TEAEs were mild to moderate in severity[3]
- Most common adverse reactions (>2%) were liver test abnormalities, diarrhea, abdominal pain, vomiting, and fat-soluble vitamin deficiency[1]
- 3 participants in the BYLVAY 120 mcg/kg/day group discontinued, with 1 due to TEAEs[3]

Through Week 72
Long-term safety profile established in PEDFIC 2[28]

Rates of SAEs[28]

Participants with any	Cohort 1A (n=37) n (%)	Cohort 1B (n=19) n (%)	Cohort 2 (n=60) n (%)
Treatment-emergent SAEs	7 (19)	5 (26)	23 (38)
Drug-related treatment-emergent SAEs	1 (3)	0	1 (2)

Common TEAEs (≥10%)[28]

Adverse reaction	Cohort 1A (n=37) n (%)	Cohort 1B (n=19) n (%)	Cohort 2 (n=60) n (%)
Cough	13 (35)	4 (21)	10 (17)
Pyrexia	12 (32)	7 (37)	16 (27)
Blood bilirubin increased	10 (27)	4 (21)	14 (23)
URTI	10 (27)	7 (37)	12 (20)
Diarrhea	9 (24)	2 (11)	17 (28)
Nasopharyngitis	9 (24)	3 (16)	9 (15)
Vomiting	2 (5)	2 (11)	10 (17)
Influenza	7 (19)	0	8 (13)
Pruritus	7 (19)	3 (16)	7 (12)
Gastroenteritis	6 (16)	1 (5)	6 (10)
INR increased	5 (14)	3 (16)	11 (18)
Hepatomegaly	4 (11)	1 (5)	1 (2)
Viral infection	4 (11)	1 (5)	7 (12)
ALT increased	3 (8)	2 (11)	6 (10)
Constipation	3 (8)	2 (11)	4 (7)
COVID-19	3 (8)	3 (16)	16 (27)
Epistaxis	3 (8)	1 (5)	6 (10)
Otitis media	3 (8)	2 (11)	2 (3)
Splenomegaly	3 (8)	2 (11)	4 (7)
Tonsilitis	3 (8)	3 (16)	1 (2)
Ear infection	2 (5)	2 (11)	3 (5)
Varicella	2 (5)	3 (16)	3 (5)
Vitamin D deficiency	2 (5)	1 (5)	8 (13)

- 35 (30%) of 116 participants experienced treatment-emergent SAEs; the majority of SAEs were assessed as unrelated to treatment with BYLVAY[28]
- The most commonly reported types of SAEs overall were infections and infestations, gastrointestinal disorders, and hepatobiliary disorders. 5 participants discontinued treatment due to SAEs[28]
- No deaths were reported[28]
- The most common reason for treatment interruption was blood bilirubin increase[28]
- Overall, 10 (9%) participants reported TEAEs that led to treatment discontinuation[28]

Additional TEAEs reported in ≥5% of participants in any cohort included abdominal pain, jaundice, rhinorrhea, AST increased, and anemia.[28]

PEDFIC 2 is an open-label extension of the PEDFIC 1 trial.[34]

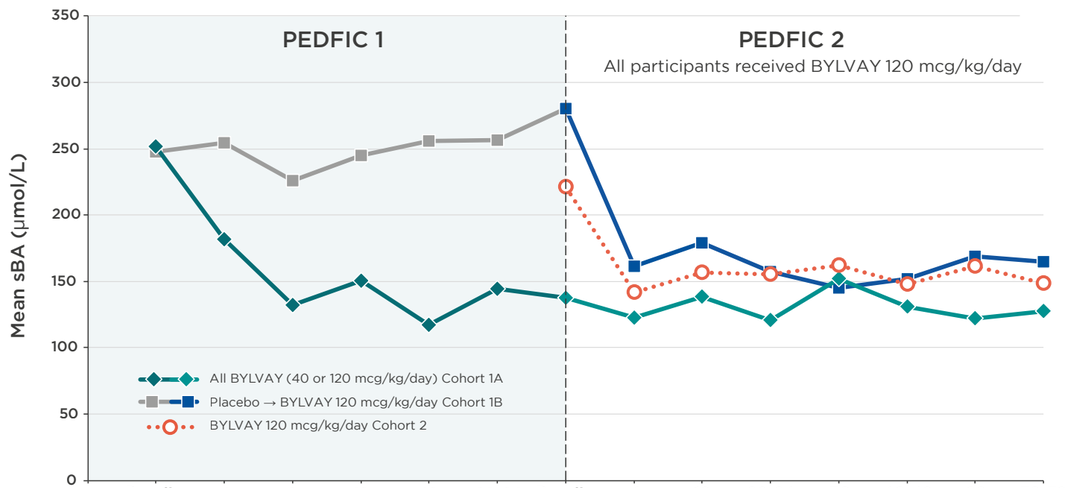
ALT=alanine aminotransferase; AST=aspartate aminotransferase; INR=international normalized ratio; SAE=serious adverse event; TEAE=treatment-emergent adverse event ; URTI=upper respiratory tract infection.

Data on reduction in serum bile acids through 96 weeks[34,39]

RAPID sBA REDUCTION

BYLVAY offers once-daily dosing and flexible administration[1]

Mean sBA levels through Week 96[34,39]



Participants, n	Baseline	4	8	12	18	22-24	Baseline	4	12	22-24	36	46-48	60	70-72
Placebo → BYLVAY	20	20	18	17	16	15	19	17	18	17	17	15	13	15
All BYLVAY→BYLVAY	42	40	37	36	26	34	37	34	35	32	29	29	27	28
BYLVAY Cohort 2	—	—	—	—	—	—	60	53	54	55	49	49	47	43

LIMITATIONS: The clinical trial was not designed to make conclusions regarding the clinical benefit of sBA reduction. The correlation between sBA and clinical outcomes is not known. sBA levels do not accurately predict bile acids in the liver. It is unknown whether the sBA assay was qualified to assess sBA levels during the analysis.

Reductions in sBA through **Week 96**[39]

sBA=serum bile acids.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS

Diarrhea

In the PFIC 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.

1 **daily dose** taken with a morning meal[1]

2 **oral formulation options:** oral pellets, capsules[1]

3 **ways to take:** swallow capsules whole; mix contents* with soft food or liquid[1]

*Pellets or capsules.

The **ONLY IBAT inhibitor** that:

- ✔ **OFFERS** once-daily dosing[40]
- ✔ **DOES NOT** require fasting or delaying of meals[40]
- ✔ **DOES NOT** require dose titration for standard treatment initiation[40]

Capsules[1] For patients weighing ≥19.5 kg

Swallow whole | Open and mix with soft food | Open and mix with liquids†

Do not crush or chew capsules

Oral Pellets[1] For patients weighing <19.5 kg

Do not swallow whole | Open and mix with soft food | Open and mix with liquids†

After mixing BYLVAY with food or liquids, discard the empty shells.[1]

†Add 1 teaspoon (5 mL) of liquid of an age-appropriate liquid.[1]

Dosing for pruritus in PFIC[1]

- **Recommended starting dose: 40 mcg/kg/day**
- If there is no improvement in pruritus after 3 months, the dosage may be increased in 40 mcg/kg increments up to 120 mcg/kg once daily
- Dose should not exceed 6 mg/day

Please see additional Important Safety Information throughout, and the full Prescribing Information.

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

Indication and Important Safety Information

INDICATION

BYLVAY is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of 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 trials, treatment-emergent elevations or worsening of liver tests occurred. Of the three PFIC patients who experienced DILI, two underwent liver transplant.

Obtain baseline liver tests because some 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 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.

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.

Fat-Soluble Vitamin (FSV) Deficiency

Fat-soluble vitamins (FSV) include vitamin A, D, E, and K. PFIC 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.

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.

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 the full Prescribing Information.

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PEDFIC 1 Key Efficacy Endpoint:
Mean percentage of pruritus assessments scored as little to no scratching (BYLVAY 40 mcg/kg/day 35%, BYLVAY 120 mcg/kg/day 30% vs placebo 13%)[1]

PEDFIC 1 Primary Endpoint:
Proportion of positive pruritus assessments over 24 weeks (All BYLVAY 55% vs placebo 30%)[3]

The mean of patients' worst weekly average scratching scores in each treatment group for each month, where the weekly average utilized the worst score from each day (morning or evening score), was assessed in PEDFIC 1.[1]

All images are actor portrayals.

INDICATION

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

Please see additional Important Safety Information throughout, and the full Prescribing Information.

IPSEN

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