

Help Your Patients ACCESS, START, AND STAY ON PAH THERAPY

Your guide to educational resources and patient support programs available when you've prescribed a Janssen product

PAH = pulmonary arterial hypertension.

Janssen Janssen Johnson

Once you've decided to prescribe OPSUMIT® (macitentan) or UPTRAVI® (selexipag) Janssen has the demonstrated expertise and support programs to help your patients ACCESS, START, and STAY on therapy.

ACCESS to Therapy

Insurance can feel burdensome. Janssen can help you obtain approval.



overall approval rate for prior authorizations.¹

• Janssen's field-based **Therapy Access Managers** and **Janssen CarePath Care Coordinators** can help educate you on how to navigate the approval process

START on Therapy

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Janssen believes that cost, coverage, and uncertainty shouldn't stand in the way of patients and their medications.

- Savings for eligible commercially insured patients: The Janssen CarePath Oral PAH Savings Program can help patients save on medication costs by paying \$5 per prescription fill
- For Medicare Part D patients—lower costs in 2024: The annual OOP cost of OPSUMIT® is expected to be comparable to that of generic ambrisentan^{2,3}
- **Prior Authorization delayed or denied?** For eligible commercially insured patients, Janssen PAH Link for OPSUMIT[®] can provide OPSUMIT[®] at no cost until insurance coverage is approved
- Not sure if OPSUMIT[®] is right for your patient? The OPSUMIT[®] Voucher Program provides a 30-day trial offer to help them become familiar with the drug

Refer to pages 4-5 for more information and program requirements.

STAY on Therapy

We help patients to connect with one-on-one educational support.

• PAH Companion withMe: patients who engage are more likely to stay on therapy^{4*}



would recommend engaging with a PAH Companion to other patients.⁵

• The Janssen-Sponsored Specialty Pharmacy UPTRAVI® Nurse Titration Education Program helps patients understand what to expect as they start therapy

Please refer to pages 6-7 for more information about these programs.

PA = prior authorization; OOP=out of pocket. *Based on 120-day persistency as of Q1 2023.

ACCESS to Therapy

Insurance can feel burdensome. Janssen can help you navigate the approval process.

When you enroll patients through Janssen CarePath:

- Janssen CarePath Care Coordinators will conduct a benefits investigation and help you navigate the approval process
- Patients will be able to enroll in Janssen-sponsored support programs







formulary exception

Therapy Access Managers (TAMs)

Our TAMs are here to provide education and assistance throughout the payer approval and patient access processes to help your patients access, start, and stay on their prescribed Janssen PAH therapy.

TAMs can:

- Identify, monitor, analyze, and triage potential challenges that impact patient access
- Offer your practice access education, including information related to payer coverage policies
- Educate your practice on payer-specific requirements Provide information on patient support programs for PA and formulary exceptions

OPSUMIT[®] has first-line formulary coverage for 93% of lives covered under **DID YOU KNOW?** Commercial and Medicare Part D insurance plans.6*

Prior Authorization Support⁺ for OPSUMIT[®] (macitentan) and UPTRAVI[®] (selexipag)

covermymeds

CoverMyMeds is a third-party service provider whose standard process allows for the secure electronic communication of prior authorization requests, inquiries, or notifications between providers, payers, and pharmacies through their online portal.

Janssen has entered into a contract with CoverMyMeds to allow pharmacies to initiate PA requests to providers upon Rx rejection, and alert the provider that the medication requires a PA.

Providers can access this functionality directly on <u>CoverMyMeds.com</u>.

*This percentage may not represent 100% of formulary lives due to data limitations.

*Janssen CarePath and CoverMyMeds do not fill out any information that requires the medical judgment of the prescriber, and only the prescriber can determine whether to submit a prior authorization for a determination.

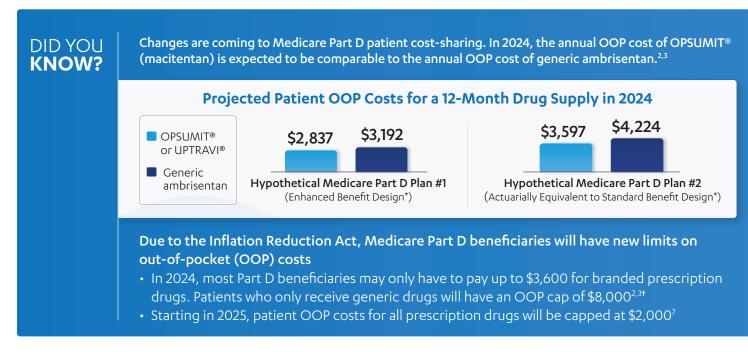
CoverMyMeds is a registered trademark of CoverMyMeds LLC. All rights reserved.

Janssen believes that cost, coverage, and uncertainty shouldn't stand in the way of patients and their medications.

Janssen CarePath Oral PAH Savings Program

Support for patients using commercial or private insurance to pay for medication

Janssen CarePath Oral PAH Savings Program can help eligible patients save on their out-of-pocket medication costs for OPSUMIT® (macitentan) and UPTRAVI® (selexipag). Your eligible patients will pay \$5 per prescription fill, with a \$20,000 maximum program benefit per calendar year across all oral PAH therapies in the program. Not valid for patients using Medicare, Medicaid, or other government-funded programs to pay for their medications. Terms expire at the end of each calendar year and may change. See program requirements.



*Part D plans must offer either the defined standard benefit or an alternative equal in value ("actuarially equivalent") and can also provide enhanced benefits. Both basic and enhanced benefit plans vary in terms of their specific benefit design, coverage, and costs, including deductibles, cost-sharing amounts, utilization management tools (ie, prior authorization, quantity limits, and step therapy), and formularies (ie, covered drugs).⁸

*Estimate is based on an actuarially equivalent benefit design. Actual patient OOP maximums for branded prescription drugs may vary between approximately \$2,800 and \$4,200 depending on their plan design and formulary tiering for their covered medications. Patients should refer to their specific plan design to understand their OOP cost obligations for prescription drugs in 2024.

Janssen CarePath can provide information about other resources that may be able to help your patients with their out-of-pocket medication costs. Visit <u>JanssenCarePath.com</u> for more information on affordability programs that may be available.

Janssen Patient Assistance Program

Patient assistance is available if your patient has commercial, employer-sponsored, or government coverage that does not fully meet their needs. Your patient may be eligible to receive their Janssen medication free of charge for up to one year if they meet the eligibility and income requirements for the Janssen Patient Assistance Program. See terms and conditions at <u>PatientAssistanceInfoPH.com</u>.

OPSUMIT® (macitentan) Voucher Program

A free 30-day trial offer is available for eligible patients to help them become familiar with OPSUMIT[®]. At the conclusion of the program, you and your patient decide whether to continue treatment.

Subject to one (1) use per lifetime for the first 30-day supply of OPSUMIT[®]. Terms expire at the end of each calendar year and may change. This Voucher Program is open to patients who have commercial insurance, government coverage, or no insurance coverage; however, there is no guarantee of continuous accessibility after the program ends. See program requirements at <u>JanssenCarePath.com/Opsumit-Voucher</u>.

Enroll your patients using the OPSUMIT® Enrollment and Prescription Form.

Janssen PAH Link for OPSUMIT®

Supports eligible, commercially insured patients until they receive coverage for their prescribed therapy

When commercial insurance coverage is delayed (>5 business days) or denied: Patients will receive OPSUMIT® **at no cost** until they receive insurance coverage approval.

See full program requirements at <u>JanssenCarePath.com/Opsumit-PAH-Link</u>

This program is not available to individuals who use any state or federal government-funded healthcare program to cover a portion of medication costs, such as Medicare, Medicaid, TRICARE, Department of Defense, or Veterans Administration. Program is for medication only. Terms expire at the end of each program year and may change.

Johnson & Johnson Patient Assistance Foundation, Inc. (JJPAF)

The Johnson & Johnson Patient Assistance Foundation, Inc. (JJPAF) is an independent, nonprofit organization. JJPAF gives eligible patients free prescription medicines donated by Johnson & Johnson companies. Patients may be eligible if they don't have insurance.

Do you have patients who may need help? They can see if they are eligible and get an application at <u>JJPAF.org</u> or call 833-919-3510 (toll free) / 308-920-4358 (direct dial), Monday through Friday, 8:00 AM to 8:00 PM ET.

STAY on Therapy

We help patients to connect with one-on-one educational support.

PAH Companion with Me

Once a decision has been made to prescribe a Janssen PAH medication, PAH Companion withMe^{*} is a suite of patient support resources customized for your patients' specific questions, needs, and interests. One-on-one educational conversations with a dedicated PAH Companion—coupled with access to current PAH tools and resources—help your patients take a more active role in their care.

DID YOU KNOW?

Over 10,000 patients have engaged in the PAH Companion withMe program. Those patients engaged are staying on therapy longer⁺ and 94% of patients would recommend the program to others.^{4-5,9}

- **Meeting patients where they are.** Newly diagnosed patients are often overwhelmed and may need additional time to review their questions and concerns. With a dedicated PAH Companion, patients have a chance to review again any disease state and Janssen product education on which they would like to get additional clarity
- **Support that matters.** As patients engage with PAH Companion withMe, they receive educational, practical, and emotional support resources as well as knowledge of new digital and PAH community tools that may help drive better health outcomes
- **Se Habla Español.** PAH Companion with Me also features a suite of Spanish resources, including a dedicated team of 5 bilingual PAH Companions that engage one-on-one with Spanish-speaking patients and their loved ones
- **Day or night, we are here.** <u>PAHcompanion.com</u> delivers a lifestyle and educational digital destination for PAH patients yearning to learn more anywhere, anytime, on any device

A dedicated PAH Companion is ready to answer your patients' questions and help them navigate their treatment experience. Patients who have enrolled can connect with their personal PAH Companion by calling 866-300-1818, Monday–Friday, 8:00 AM–9:00 PM ET.

PAH Companion withMe is limited to education for patients about their PAH therapy, its administration, and/or their disease, and is not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, or provide case management services.

*PAH Companion withMe is only for patients on certain Janssen PAH medications and requires a completed patient authorization form to enroll. *Based on 120-day persistency as of Q1 2023.

Janssen Sponsored Specialty Pharmacy (SP) UPTRAVI® (selexipag) Titration Education Program

After you, as the treating healthcare professional, have made the decision to prescribe UPTRAVI®, you may choose for your patient to receive nurse education support as they start therapy.

For patients to receive this service, you must check the box in section 4 of the enrollment form to opt in to the nurse support and titration education program.

Within 48 hours of your patient's receipt of their first UPTRAVI® shipment, an SP Nurse can have an interaction with your patient.

During these visits with your patient, the nurse can:

- Educate the patient on what to expect as they start therapy with UPTRAVI®
- Ensure the patient's understanding of reaching their personal dose
- Educate the patient to help address potential misconceptions about UPTRAVI® dosing
- Provide the patient and/or their caregiver with recommendations on when to call their HCP

The information provided is educational in nature and not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, provide case management services, or serve as a reason to prescribe.

Please see Important Safety Information on pages 13-15 and full Prescribing Information, for UPTRAVI®.

You know your patients. We know how to support them.



Indication and Important Safety Information for OPSUMIT[®] (macitentan)

INDICATION

OPSUMIT[®] is an endothelin receptor antagonist (ERA) indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to reduce the risks of disease progression and hospitalization for PAH.

Effectiveness was established in a long-term study in PAH patients with predominantly WHO Functional Class II-III symptoms treated for an average of 2 years. Patients had idiopathic and heritable PAH (57%), PAH caused by connective tissue disorders (31%), and PAH caused by congenital heart disease with repaired shunts (8%).

IMPORTANT SAFETY INFORMATION

BOXED WARNING: EMBRYO-FETAL TOXICITY

- Do not administer OPSUMIT[®] to a pregnant female because it may cause fetal harm.
- Females of reproductive potential: Exclude pregnancy before the start of treatment, monthly during treatment, and 1 month after stopping treatment. Prevent pregnancy during treatment and for one month after stopping treatment by using acceptable methods of contraception.
- For all female patients, OPSUMIT[®] is available only through a restricted program called the Macitentan Risk Evaluation and Mitigation Strategy (REMS).

CONTRAINDICATIONS

Pregnancy: OPSUMIT[®] may cause fetal harm when administered to a pregnant woman. OPSUMIT[®] is contraindicated in females who are pregnant. If OPSUMIT[®] is used during pregnancy, advise the patient of the potential risk to a fetus.

Hypersensitivity: OPSUMIT[®] is contraindicated in patients with a history of a hypersensitivity reaction to macitentan or any component of the product.

Please see Important Safety Information on pages 9-12 and full <u>Prescribing Information</u>, including BOXED WARNING, for OPSUMIT[®].

Important Safety Information for OPSUMIT® (macitentan) (cont'd)

WARNINGS AND PRECAUTIONS

Embryo-fetal Toxicity and Macitentan REMS Program

Due to the risk of embryo-fetal toxicity, OPSUMIT[®] is available for females only through a restricted program called the Macitentan REMS Program. For females of reproductive potential, exclude pregnancy prior to initiation of therapy, ensure use of acceptable contraceptive methods, and obtain monthly pregnancy tests.

Notable requirements of the Macitentan REMS Program include:

- Prescribers must be certified with the program by enrolling and completing training.
- All females, regardless of reproductive potential, must enroll in the Macitentan REMS Program prior to initiating OPSUMIT[®]. Male patients are not enrolled in the REMS.
- Females of reproductive potential must comply with the pregnancy testing and contraception requirements.
- Pharmacies must be certified with the program and must only dispense to patients who are authorized to receive OPSUMIT[®].

Hepatotoxicity

- ERAs have caused elevations of aminotransferases, hepatotoxicity, and liver failure. The incidence of elevated aminotransferases in the SERAPHIN study >3 x ULN was 3.4% for OPSUMIT® vs 4.5% for placebo, and >8 x ULN was 2.1% vs 0.4%, respectively. Discontinuations for hepatic adverse events were 3.3% for OPSUMIT® vs 1.6% for placebo.
- Obtain liver enzyme tests prior to initiation of OPSUMIT® and repeat during treatment as clinically indicated.
- Advise patients to report symptoms suggesting hepatic injury (nausea, vomiting, right upper quadrant pain, fatigue, anorexia, jaundice, dark urine, fever, or itching).
- If clinically relevant aminotransferase elevations occur, or if elevations are accompanied by an increase in bilirubin >2 x ULN, or by clinical symptoms of hepatotoxicity, discontinue OPSUMIT[®]. Consider re-initiation of OPSUMIT[®] when hepatic enzyme levels normalize in patients who have not experienced clinical symptoms of hepatotoxicity.

Please see Important Safety Information on pages 9-12 and full <u>Prescribing Information</u>, including BOXED WARNING, for OPSUMIT[®].

Important Safety Information for OPSUMIT® (macitentan) (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Fluid Retention

- Peripheral edema and fluid retention are known consequences of PAH and ERAs. In the pivotal PAH study SERAPHIN, edema was reported in 21.9% of the OPSUMIT[®] group vs 20.5% for placebo.
- Patients with underlying left ventricular dysfunction may be at particular risk for developing significant fluid retention after initiation of ERA treatment. In a small study of pulmonary hypertension due to left ventricular dysfunction, more patients in the OPSUMIT[®] group developed significant fluid retention and had more hospitalizations due to worsening heart failure compared to placebo. Postmarketing cases of edema and fluid retention occurring within weeks of starting OPSUMIT[®], some requiring intervention with a diuretic or hospitalization for decompensated heart failure, have been reported.
- Monitor for signs of fluid retention after OPSUMIT® initiation. If clinically significant fluid retention develops, evaluate the patient to determine the cause and the possible need to discontinue OPSUMIT®.

Hemoglobin Decrease

- Decreases in hemoglobin concentration and hematocrit have occurred following administration of other ERAs and in clinical studies with OPSUMIT[®]. These decreases occurred early and stabilized thereafter.
- In the SERAPHIN study, OPSUMIT[®] caused a mean decrease in hemoglobin (from baseline to 18 months) of about 1.0 g/dL vs no change in the placebo group. A decrease in hemoglobin to below 10.0 g/dL was reported in 8.7% of the OPSUMIT[®] group vs 3.4% for placebo. Decreases in hemoglobin seldom require transfusion.
- Initiation of OPSUMIT[®] is not recommended in patients with severe anemia. Measure hemoglobin prior to initiation of treatment and repeat during treatment as clinically indicated.

Pulmonary Edema with Pulmonary Veno-occlusive Disease (PVOD)

Should signs of pulmonary edema occur, consider the possibility of associated PVOD. If confirmed, discontinue OPSUMIT[®].

Please see Important Safety Information on pages 9-12 and full <u>Prescribing Information</u>, including BOXED WARNING, for OPSUMIT[®].

Important Safety Information for OPSUMIT® (macitentan) (cont'd)

Decreased Sperm Counts

OPSUMIT[®], like other ERAs, may have an adverse effect on spermatogenesis. Counsel men about potential effects on fertility.

ADVERSE REACTIONS

Most common adverse reactions (more frequent than placebo by ≥3%) were anemia (13% vs 3%), nasopharyngitis/pharyngitis (20% vs 13%), bronchitis (12% vs 6%), headache (14% vs 9%), influenza (6% vs 2%), and urinary tract infection (9% vs 6%).

DRUG INTERACTIONS

- Strong inducers of CYP3A4 such as rifampin significantly reduce macitentan exposure. Concomitant use of OPSUMIT® with strong CYP3A4 inducers should be avoided.
- Strong inhibitors of CYP3A4 like ketoconazole approximately double macitentan exposure. Many HIV drugs like ritonavir are strong inhibitors of CYP3A4. Avoid concomitant use of OPSUMIT® with strong CYP3A4 inhibitors. Use other PAH treatment options when strong CYP3A4 inhibitors are needed as part of HIV treatment.
- Moderate dual inhibitors of CYP3A4 and CYP2C9 such as fluconazole and amiodarone are predicted to increase macitentan exposure. Avoid concomitant use of OPSUMIT[®] with moderate dual inhibitors of CYP3A4 and CYP2C9.
- Concomitant treatment of both a moderate CYP3A4 inhibitor and moderate CYP2C9 inhibitor with OPSUMIT® should also be avoided.

Please see Important Safety Information on pages 9-12 and full <u>Prescribing Information</u>, including BOXED WARNING, for OPSUMIT[®].

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Indication and Important Safety Information for UPTRAVI® (selexipag)

INDICATION

UPTRAVI® is indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH.

Effectiveness of UPTRAVI® Tablets was established in a long-term study in PAH patients with WHO Functional Class II-III symptoms.

Patients had idiopathic and heritable PAH (58%), PAH associated with connective tissue disease (29%), and PAH associated with congenital heart disease with repaired shunts (10%).

Important Safety Information

CONTRAINDICATIONS

Concomitant use of strong inhibitors of CYP2C8 (eg, gemfibrozil) with UPTRAVI® is contraindicated.

Hypersensitivity to the active substance or to any of the excipients is contraindicated.

WARNINGS AND PRECAUTIONS

Pulmonary Edema with Pulmonary Veno-Occlusive Disease (PVOD)

Should signs of pulmonary edema occur, consider the possibility of associated PVOD. If confirmed, discontinue UPTRAVI®.

ADVERSE REACTIONS

Adverse reactions more frequent compared to placebo (≥3%) seen with UPTRAVI® Tablets are headache (65% vs 32%), diarrhea (42% vs 18%), jaw pain (26% vs 6%), nausea (33% vs 18%), myalgia (16% vs 6%), vomiting (18% vs 9%), pain in extremity (17% vs 8%), flushing (12% vs 5%), arthralgia (11% vs 8%), anemia (8% vs 5%), decreased appetite (6% vs 3%), and rash (11% vs 8%).

These adverse reactions are more frequent during the dose titration phase.

Hyperthyroidism was observed in 1% (n=8) of patients on UPTRAVI® Tablets and in none of the patients on placebo.

Please see Important Safety Information on pages 13-15 and full <u>Prescribing Information</u> for UPTRAVI®.

Important Safety Information for UPTRAVI® (selexipag) (cont'd)

DRUG INTERACTIONS

CYP2C8 Inhibitors

Concomitant administration with gemfibrozil, a strong inhibitor of CYP2C8, doubled exposure to selexipag and increased exposure to the active metabolite by approximately 11-fold. Concomitant use of UPTRAVI® with strong inhibitors of CYP2C8 is contraindicated.

Concomitant administration of UPTRAVI® with clopidogrel, a moderate inhibitor of CYP2C8, had no relevant effect on the exposure to selexipag and increased the exposure to the active metabolite by approximately 2.7-fold. Reduce the dosing of UPTRAVI® to once daily in patients on a moderate CYP2C8 inhibitor.

CYP2C8 Inducers

Concomitant administration with an inducer of CYP2C8 and UGT 1A3 and 2B7 enzymes (rifampin) halved exposure to the active metabolite. Increase UPTRAVI® dose, up to twice, when co-administered with rifampin. Reduce UPTRAVI® when rifampin is stopped.

DOSAGE AND ADMINISTRATION

Recommended Dosage

Recommended starting dose is 200 mcg twice daily for UPTRAVI® Tablets. Tolerability may be improved when taken with food. Increase by 200 mcg twice daily, usually at weekly intervals, to the highest tolerated dose up to 1600 mcg twice daily. If dose is not tolerated, reduce to the previous tolerated dose.

Patients With Hepatic Impairment

For patients with moderate hepatic impairment (Child-Pugh class B), the starting dose of UPTRAVI® Tablets is 200 mcg <u>once daily</u>. Increase by 200 mcg <u>once daily</u> at weekly intervals, as tolerated. Avoid use of UPTRAVI® in patients with severe hepatic impairment (Child-Pugh class C).

Co-administration With Moderate CYP2C8 Inhibitors

When co-administered with moderate CYP2C8 inhibitors (eg, clopidogrel, deferasirox and teriflunomide), reduce the dosing of UPTRAVI® to <u>once daily</u>.

Please see Important Safety Information on pages 13-15 and full <u>Prescribing Information</u> for UPTRAVI®.

Important Safety Information for UPTRAVI® (selexipag) (cont'd)

Dosage Strengths

UPTRAVI® tablet strengths:

200, 400, 600, 800, 1000, 1200, 1400, and 1600 mcg.

Additional Important Safety Information for UPTRAVI® IV

Use UPTRAVI® for injection in patients who are temporarily unable to take oral therapy.

Administer UPTRAVI® for injection twice daily by intravenous infusion at a dose that corresponds to the patient's current dose of UPTRAVI® Tablets (see Table 1 in full Prescribing Information). Administer UPTRAVI® for injection as an 80-minute intravenous infusion.

Adverse Reactions: Infusion-site reactions (infusion-site erythema/redness, pain and swelling) were reported with UPTRAVI® for injection.

Please see Important Safety Information on pages 13-15 and full <u>Prescribing Information</u> for UPTRAVI®.

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References: 1. Data on file. Actelion Pharmaceuticals US, Inc. Janssen PH HUB Transaction Data. August 2023. **2.** 2024 PDP-Planner: Medicare Part D Donut Hole Calculator. Q1 Group LLC. https://q1medicare.com/PartD-PartDCoverageGapCalculator2024.php **3.** Data on File. Actelion Pharmaceuticals US, Inc. 2024 Medicare Part D OOP Cost Modeling. August 2023. **4.** Data on file. Actelion Pharmaceuticals US, Inc. Janssen Insights and Analytics Team. September 2023. **5.** Data on file. Actelion Pharmaceuticals US, Inc. Janssen PAH Q2 QBR 2022 Final. April 2023. **6.** Data on file. Actelion Pharmaceuticals US, Inc. Managed Markets Insight and Technology LLC [™], a Trademark of MMIT, as of September 2023. **7.** Inflation Reduction Act and Medicare. CMS. https://www.cms. gov/inflation-reduction-act-and-medicare **8.** An overview of the Medicare Part D Prescription Drug Benefit. Kaiser Family Foundation website. Published October 19, 2022. Accessed September 18, 2023. https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescriptiondrug-benefit/ **9.** Data on file. Actelion Pharmaceuticals US, Inc. Janssen Commercial Strategy and Operations Team. September 2023.

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