Looking for a primary immunodeficiency (PI) treatment?

Meet the only monthly* subQ IG treatment.

*Every 3 or 4 weeks. IG=immune globulin.

See what makes HyQvia[®] [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] different.

What is HyQvia?

HyQvia is a liquid medicine that is given under the skin (subcutaneously) to treat primary immunodeficiency (PI) in people 2 years and older.

IMPORTANT SAFETY INFORMATION

What is the most important information that I should know about HyQvia?

- HyQvia can cause blood clots.
- Call your healthcare professional (HCP) if you have pain, swelling, warmth, redness, or a lump in your legs or arms, other than at the infusion site(s), unexplained shortness of breath, chest pain or discomfort that worsens on deep breathing, unexplained rapid pulse, numbness or weakness on one side of the body.

Please see additional Important Safety Information throughout, click for <u>Information for Patients</u>, and discuss with your HCP.

HyQvia [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase]

Let's start with the basics. What is primary immunodeficiency (PI)?

Pl is a term used to describe a group (hundreds!) of lifelong disorders, and unfortunately, they all cause the immune system to not work right, making it harder for your body to fight infections.

So how is PI treated? Commonly with immune globulin, or IG. Chances are, it's already been a long, overwhelming road to get to this point. And now, with the help of your doctor, you have to decide what treatment may be best for you. Ready to say hy?

Your genes tell a story.

Pl is usually genetic, which means there is a defect in one or more of your genes. This also means that Pl diseases can run in families. However, Pl isn't contagious, so it's not like you can catch it from someone like a cold or the flu.



Common types of PI

While there are many types of PI, some common types include selective IgA deficiency, common variable immune deficiency (CVID), X-linked agammaglobulinemia (XLA), and severe combined immunodeficiency (SCID). It's commonly managed with IG to provide protection from infection. You'll decide what may be the best treatment for you with your doctor.

Get immune globulin (IG) once a month,* subcutaneously.

*Every 3 or 4 weeks.

IG is a term you'll hear and read about often. IG contains antibodies you can think of as warriors, helping your body fight infections by replacing antibodies that are missing or not working properly.

Antibodies (also known as immune globulin, or IG) are an important part of your immune system because they help your body fight infections. Some people with PI have trouble producing antibodies. For others with PI, their antibodies don't work properly. So, a common treatment is IG treatment, which is made up of antibodies donated by healthy people.

Here's where treatment comes in for those with PI. Over time, your body uses up these infused antibodies. This means that you need IG regularly so that you have a constant supply of antibodies ready to help your body defend against infections.

IMPORTANT SAFETY INFORMATION (continued)

What is the most important information that I should know about HyQvia? (continued)

- Your HCP may perform blood tests regularly to check your IgG level.
- Do not infuse HyQvia into or around an infected or red swollen area because it can cause infection to spread.

Who should not take HvQvia?

Do not take HyQvia if you:

• Are allergic to IgG, hyaluronidase, other blood products, or any ingredient in HyQvia.

You can infuse IG intravenously (IV) or subcutaneously (subQ) to treat PI.

With HyQvia, you infuse subcutaneously, or the subQ way, which means the needle goes just under your skin (and not into your vein). With proper training from a nurse, you can infuse HyQvia at home. This lets you keep the schedule of an IVIG therapy (every 3-4 weeks) with the convenience of infusing in the comfort of your own home.

Or, there's infusing with an IV (also known as IVIG), which is a bigger needle into a vein rather than the subQ space under your skin. When you infuse with an IV, you often need to travel to and from an infusion center so a nurse can complete your infusion.

Here's a comparison of needle sizes for each:



For illustrative purposes. Actual needle sizes may vary.

What does the pump do?

With HyQvia, you'll use either a peristaltic pump or a syringe pump driver. Both pumps control the rate in which IG enters your body. That's called your infusion rate.

IMPORTANT SAFETY INFORMATION (continued)

What should I avoid while taking HyQvia?

 HyQvia can make vaccines (like measles/mumps/rubella or chickenpox vaccines) not work as well for you. Before you get any vaccines, tell your HCP that you take HyQvia.

Please see additional Important Safety Information throughout, click for Information for Patients, including Warning about Blood Clots, and discuss with your HCP.





What makes the infusion experience different?





IG

Hv

We're the only monthly* subQ IG treatment.

As opposed to IV infusion, HyQvia is administered in the subQ space. That means that the needle to infuse is not as long and the medicine is infused just under your skin. And, depending on the infusion schedule you and your doctor work out, there's a possibility you can go up to 28 days between infusions, unlike other subQ IG therapies where more frequent infusions are necessary.

in your body naturally.

Hyaluronidase, or Hy, is the first part of your infusion. It allows a larger amount of IG to reach your subQ tissue and be absorbed into your bloodstream to help your body fight infections—so you only have to infuse once a month.*

The average infusion time is about 2 hours, once a month.*

As opposed to infusing IG with an IV, which takes about 3-4 hours + your travel time to and from an infusion center. Infusions with an IV usually take place at an infusion center. HyQvia can be given at home, after training, but some people still prefer to go into their doctor's office for their infusion.



When it comes to actually getting your treatment, you have options.

Why shouldn't you? Not everything is one size fits all, especially when it comes to something as important as your treatment and your comfort level. With flexible administration options, you choose whether you want to infuse in the comfort of your own home (with training, of course), at an infusion center, by yourself, or with a nurse. Check with your insurance carrier to see what's covered.

*Every 3 or 4 weeks.

IMPORTANT SAFETY INFORMATION (continued) What should I tell my HCP before I start using or while using HyQvia?

Tell your HCP if you:

- Have or had any kidney, liver, or heart problems or history of blood clots because HyQvia can make these problems worse.
- Have IgA deficiency or a history of severe allergic reactions to IgG or other blood products.
- Are pregnant, trying to become pregnant or are breast feeding. It is not known whether HyQvia can harm the unborn baby or breastfed infant.

Please see additional Important Safety Information throughout, click for Information for Patients, including Warning about Blood Clots, and discuss with your HCP.

HyQvia is different because of hyaluronidase, or Hy, which can be found



Protection from infection so you can focus on more of what you love.

HyQvia is the only once-monthly* subQ IG treatment. It also provides protection from infection and consistent IG levels, like other subQ therapies. This means the antibody-packed IG helps your body fight off infections throughout the month.

HyQvia and acute serious bacterial infections (ASBIs) were studied in a clinical trial of 83 adults with PI. The main goal was to measure how many ASBIs people experienced over the course of 1 year. ASBIs are short-term but serious infections caused by bacteria that require immediate medical care. The FDA standard for efficacy-that is, if an immunoglobulin works-is less than 1 ASBI per year. In the HyQvia clinical trial, people experienced significantly less than that, 0.025 ASBI per patient-year. ASBIs included 2 episodes of pneumonia. Both episodes were treated as outpatients with oral antibiotics. An additional episode of pneumonia requiring hospitalization occurred during the ramp-up.

*Every 3 or 4 weeks.

IMPORTANT SAFETY INFORMATION (continued)

What are the possible or reasonably likely side effects of HyQvia?

HyQvia can cause serious side effects. If any of the following problems occur after starting HyQvia, stop the infusion immediately and contact your HCP or call emergency services:

- Hives, swelling in the mouth or throat, itching, trouble breathing, wheezing, fainting or dizziness. These could be signs of a serious allergic reaction.
- Bad headache with nausea, vomiting, stiff neck, fever, and sensitivity to light. These could be signs of irritation and swelling of the lining around your brain.
- Reduced urination, sudden weight gain, or swelling in your legs. These could be signs of a kidney problem.

Side effects are a potential part of treatment.

Local side effects, which happen at the infusion site, include mild or moderate pain, redness, swelling, and itching. Approximately 99% of local side effects were considered mild to moderate in a clinical trial. Mild side effects cause temporary discomfort that goes away on its own, or with little medical intervention. Moderate side effects cause a slight decline in function that goes away on its own, or with little medical intervention, and have no further consequences. Severe side effects result in impairment of function and can lead to temporary inability to resume a normal lifestyle as it requires prolonged medical intervention and/or results in further consequences.

General side effects throughout the body, also known as systemic, may occur within 72 hours. The most common side effects that were observed in the clinical trial were headache, antibody formation against Hy, fatigue, nausea, fever, and vomiting.



The most common general side effects (systemic) for HyQvia vs IVIG 10% (Human):

IMPORTANT SAFETY INFORMATION (continued)

What are the possible or reasonably likely side effects of HyQvia? (continued) HvQvia can cause serious side effects. If any of the following problems occur after starting HyQvia, stop the infusion immediately and contact your HCP or call emergency services:

- Pain, swelling, warmth, redness, or a lump in your legs or arms, other than at the infusion site(s). These could be signs of a blood clot.
- Brown or red urine, fast heart rate, yellow skin or eyes. These could be signs of a liver or blood problem.

Please see additional Important Safety Information throughout, click for Information for Patients, including Warning about Blood Clots, and discuss with your HCP.

The rate is the total number of systemic side effects divided by the total number of infusions.

Patients on IVIG received treatment for a median of 91 days. Patients on HyQvia received treatment for a median of 42 days during the dose ramp-up period, and then for a median of 366 days.

These side effects happened within 72 hours of infusion and/or were thought to be caused by the infusion.



Ready to say hy

Start the conversation with your doctor to see if HyQvia may be right for you. At HyQvia.com, there's an entire section (under the "What is HyQvia?" tab and then "Talking With Your Doctor") dedicated to helping you have a conversation with your doctor. It's a quick questionnaire where you check boxes off. Checking off those boxes will help guide your conversation and help you and your doctor figure out what may be best for you, together. When you're finished, you can even save a pdf to have your answers handy for your next appointment.

IMPORTANT SAFETY INFORMATION (continued)

What are the possible or reasonably likely side effects of HyQvia? (continued)

HyQvia can cause serious side effects. If any of the following problems occur after starting HvQvia, stop the infusion immediately and contact your HCP or call emergency services:

- Chest pain or trouble breathing, blue lips or extremities. These could be signs of a serious heart or lung problem.
- Fever over 100°F. This could be a sign of an infection.



Section 1: My concerns

What is your biggest concern about your infusion treatments?

- My schedule: the time infusions take out of my day-to-day routine; difficulty getting appointments or refills
- My comfort: with needles, needle size, and number of needlesticks; recovering enough to do normal activities after an infusion
- My independence: being comfortable infusing myself or depending on someone else to infuse for
- My safety: whether someone else is doing it or me; at home or at an infusion center/hospital/office
- Thinking of something else? Tell us:

Type your answer here IMPORTANT SAFETY INFORMATION

There's a free trial program.

It's called **HelloHYQVIA**, and if you're eligible,* it lets you try HyQvia for free to see if it's right for you. As part of the trial, the entire cost of your first three infusions and supplies during your ramp-up period is free. Your doctor can take the first step to enroll you, so be sure to ask.

Here are the benefits of HelloHYQVIA:

- It allows you and your doctor to determine if HyQvia is right for you
- The entire cost of your first three HyQvia infusions is free, including the pump, supplies, and initial infusion training. Everything will be shipped directly to your home
- Your Specialty Pharmacy Nursing Network (SPNN) nurse will not only guide you through infusing HyQvia, but will also work with you to optimize your HyQvia infusion parameters. Whether that's in-person or virtual visits is up to you

*To be eligible, you must:

- Be a patient with an ICD-10-verified diagnosis of primary immunodeficiency (PI)
- Be a new patient not currently using HyQvia and haven't been previously enrolled in the HelloHYQVIA program

Additional terms and conditions apply. Visit **HyQvia.com** to learn more and download a brochure with more info.

IMPORTANT SAFETY INFORMATION (continued)

What are the possible or reasonably likely side effects of HyQvia? (continued)

After HyQvia infusion a temporary, soft swelling may occur around the infusion site, which may last 1 to 3 days, due to the volume of fluid infused. The following possible side effects may occur at the site of infusion and generally go away within a few hours, and are less likely after the first few infusions.

- Mild or moderate pain
 Redness
 Swelling
 Itching The most common side effects of HyQvia are:
- Headache
 Fatique
 Nausea
 Fever
 Vomiting

Antibodies to the hyaluronidase component of HyQvia were formed in some patients taking HyQvia. It is not known if there is any long-term effect. In theory, these antibodies could react with your body's own hyaluronidase (PH20). PH20 is present in the male reproductive tract. So far, these antibodies have not been associated with increased or new side-effects.

These are not all the possible side effects. Talk to your HCP about any side effect that bothers you or that does not go away.

Please see additional Important Safety Information throughout, click for Information for Patients, including Warning about Blood Clots, and discuss with your HCP.

HyQvia

[Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase]

What is HyQvia?

HyQvia is a liquid medicine that is given under the skin (subcutaneously) to treat primary immunodeficiency (PI) in people 2 years and older.

IMPORTANT SAFETY INFORMATION

What is the most important information that I should know about HyQvia?

- HyQvia can cause blood clots.
- Call your healthcare professional (HCP) if you have pain, swelling, warmth, redness, or a lump in your legs or arms, other than at the infusion site(s), unexplained shortness of breath, chest pain or discomfort that worsens on deep breathing, unexplained rapid pulse, numbress or weakness on one side of the body.
- Your HCP may perform blood tests regularly to check your IgG level.
- Do not infuse HyQvia into or around an infected or red swollen area because it can cause infection to spread.

Who should not take HyQvia?

Do not take HyQvia if you:

• Are allergic to IgG, hyaluronidase, other blood products, or any ingredient in HyQvia.

What should I avoid while taking HyQvia?

 HyQvia can make vaccines (like measles/mumps/rubella or chickenpox vaccines) not work as well for you. Before you get any vaccines, tell your HCP that you take HyQvia.

What should I tell my HCP before I start using or while using HyQvia?

Tell your HCP if you:

- Have or had any kidney, liver, or heart problems or history of blood clots because HyQvia can make these problems worse.
- Have IgA deficiency or a history of severe allergic reactions to IgG or other blood products.
- Are pregnant, trying to become pregnant or are breast feeding. It is not known whether HyQvia can harm the unborn baby or breastfed infant.

What are the possible or reasonably likely side effects of HyQvia?

HyQvia can cause serious side effects. If any of the following problems occur after starting HyQvia, stop the infusion immediately and contact your HCP or call emergency services:

• Hives, swelling in the mouth or throat, itching, trouble breathing, wheezing, fainting or dizziness. These could be signs of a serious allergic reaction.

IMPORTANT SAFETY INFORMATION (continued)

What are the possible or reasonably likely side effects of HvQvia? (continued)

- Bad headache with nausea, vomiting, stiff neck, fever, and sensitivity to light. These could be signs of irritation and swelling of the lining around your brain.
- Reduced urination, sudden weight gain, or swelling in your legs. These could be signs of a kidney problem.
- Pain, swelling, warmth, redness, or a lump in your legs or arms, other than at the infusion site(s). These could be signs of a blood clot.
- Brown or red urine, fast heart rate, yellow skin or eyes. These could be signs of a liver or blood problem.
- Chest pain or trouble breathing, blue lips or extremities. These could be signs of a serious heart or lung problem.
- Fever over 100°F. This could be a sign of an infection.

After HyQvia infusion a temporary, soft swelling may occur around the infusion site, which may last 1 to 3 days, due to the volume of fluid infused. The following possible side effects may occur at the site of infusion and generally go away within a few hours, and are less likely after the first few infusions.

Mild or moderate pain
 Redness
 Swelling
 Itching

The most common side effects of HyQvia are:

Headache
 Fatique
 Nausea
 Fever
 Vomiting

Antibodies to the hyaluronidase component of HyQvia were formed in some patients taking HyQvia. It is not known if there is any long-term effect. In theory, these antibodies could react with your body's own hyaluronidase (PH20). PH20 is present in the male reproductive tract. So far, these antibodies have not been associated with increased or new side-effects.

These are not all the possible side effects. Talk to your HCP about any side effect that bothers you or that does not go away.

For additional safety information, click for Information for Patients and discuss with your HCP.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.



We understand this is a big deal. That's why there are resources.

And those aren't empty words. There are opportunities for you to get real, honest, helpful support should you ever need it. There's also co-pay assistance, if you're eligible.

my g source

This is a whole community committed to helping each other and loved ones manage a life with PI. With more than 52,000 members, this online community helps you and caregivers find information about PI and connect with IG Community Support Team Advocates-people who live with or love someone with PI.

Want to connect with an advocate? Call 1-855-250-5111 to talk or visit MylgSource.com to learn more.



Help is just a tap or call away.

When prescribed a Takeda treatment—whether it's new to you, you've been on treatment, or you're taking care of someone else—Takeda Patient Support is here to help.

The Takeda Patient Support Co-Pay Assistance Program may cover

of your out-of-pocket costs if vou're eligible*

Not enrolled or need assistance?

You can join Takeda Patient Support in a few simple steps. Visit TakedaPatientSupport.com or scan this QR code.

Our support specialists are never more than a tap or a call away. Reach us at **1-866-861-1750**. Monday through Friday, 8 AM to 8 PM ET.



*IMPORTANT NOTICE: The Takeda Patient Support Co-Pay Assistance Program (the Program) is not valid for prescriptions eligible to be reimbursed, in whole or in part, by Medicaid, Medicare (including Medicare Part D), Tricare, Medigap, VA, DoD, or other federal or state programs (including any medical or state prescription drug assistance programs). No claim for reimbursement of the out-of-pocket expense amount covered by the Program shall be submitted to any third party payer, whether public or private. The Program cannot be combined with any other rebate/coupon, free trial, or similar offer. Copayment assistance under the Program is not transferable. The Program only applies in the United States, including Puerto Rico and other U.S. territories, and does not apply where prohibited by law, taxed, or restricted. This does not constitute health insurance. Void where use is prohibited by your insurance provider. If your insurance situation changes you must notify the Program immediately at 1-866-861-1750. Coverage of certain administration charges will not apply for patients residing in states where it is prohibited by law. Takeda reserves the right to rescind, revoke, or amend the Program at any time without notice.

C A co-pay assistance program

Your dedicated specialist will walk you through the insurance process and help you understand what's covered.

G Help getting your medicine

We can help you receive your treatment by getting your medication when you need it.



C Nursing support

This can be arranged if you have questions about your treatment. Our nurses cannot provide medical advice.

C Education about your condition

We can help you better understand your condition and treatment, and direct you to support resources and education that you can discuss with your healthcare provider.

C Ongoing support

We're here for you. We'll share emails and texts with tips and timely info throughout your treatment.

You can always say

Ask your doctor about HyQvia. Until then, learn more at **HyQvia.com**.

IMPORTANT SAFETY INFORMATION

What is the most important information that I should know about HyQvia?

- HyQvia can cause blood clots.
- Call your healthcare professional (HCP) if you have pain, swelling, warmth, redness, or a lump in your legs or arms, other than at the infusion site(s), unexplained shortness of breath, chest pain or discomfort that worsens on deep breathing, unexplained rapid pulse, numbness or weakness on one side of the body.

Please see additional Important Safety Information throughout, click for <u>Information for Patients</u>, and discuss with your HCP.



©2024 Takeda Pharmaceuticals U.S.A., Inc., 300 Shire Way, Lexington, MA 02421. 1-877-TAKEDA-7 (1-877-825-3327). All rights reserved. TAKEDA®, the TAKEDA Logo®, and the TAKEDA Patient Support Logo® are registered trademarks of Takeda Pharmaceutical Company Limited. HYQVIA® is a registered trademark of Baxalta Incorporated. MYIGSOURCE™ is a trademark of Baxalta Incorporated. US-HYQ-0486v4.0 02/24

