

## Let's walk through the infusion process together.

#### This is your Step-by-Step Infusion Guide.

Thank you for trusting HyQvia to help you manage and treat your Pl. We know that managing Pl is no small undertaking. That's why we've created hy5—featuring five sections to help you learn how to self-infuse.

This guide is intended for use only as a supplement to in-person training from your healthcare professional. Do not infuse HyQvia until you have been trained, have read the Information for Patients, and are comfortable that you can perform the steps on your own.

### What is HyQvia® [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase]?

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 Information For Patients, and discuss with your HCP.



The HyQvia infusion process, and all of its steps, are split up into five sections that we call **hy5**. Why? It's a simple, clear way to not only help you get familiar with the infusion process, but also to remember the sections and the steps that fall into those sections. You may have already had or will have training sessions with a nurse to learn how to self-infuse, and that'll help you learn and become familiar with infusing too. And remember, talk to your doctor about any questions or concerns you have, whether you're just starting infusing or have been infusing for a while.



#### Ready to get started?

Scroll down to get familiar with your supplies.

#### **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.

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

This guide is not meant to be stand-alone instructions but rather a supplement to in-person training from a healthcare professional. Please refer to your HyQvia Information for Patients for a complete list of steps.





## Infusing with a peristaltic pump.

Our goal is to make sure that you feel confident in your ability to complete your infusions in the comfort of your own home.

#### IMPORTANT SAFETY INFORMATION (continued)

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.

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

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with Recombinant Human Hyaluronidase]

#### What you'll need



#### Below are the supplies you will need to infuse HyQvia.

It may seem a bit overwhelming at first, but this guide will walk you through the supplies you'll be using and the infusion process. Something to know – the supplies that you receive from your pharmacy may look different, and that's OK. Supplies may vary based on what brands the specialty pharmacy has in stock.



HyQvia vial(s)
The number of vials you will have will depend on your prescribed dose.



Alcohol swabs, antibacterial cleaner, soap, tape, and bandages. Gloves can be used if recommended by your doctor



Syringe(s)



Sterile tip caps—1 per syringe



Needle or needle-less transfer device\*—
1 per HyQvia vial



Subcutaneous needle set with a clear dressing—1 per infusion site



Pooling bag



Gravity fill set with vented spike and sterile cap



Peristaltic infusion pump, pump tubing, power supply, and manual



**Optional:** Saline infusion bag (if required by your doctor)



Sharps container



Wellness Journal

Over time, you'll become familiar with your supplies.



## Get ready

Inspect your vials	6
Gather your supplies	7
Wash hands and sanitize work area	g

#### 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, including Warning about Blood Clots, click for <u>Information For Patients</u>, and discuss with your HCP.







#### **Inspect your vials**



- Inspect your vials.
  - Always make sure you have the correct dose that your doctor prescribed.
  - Do not use if vials are missing a protective cap or are broken.
  - Check the expiration date, and make sure they're not expired. Don't ever use them if they're past the expiration date.
  - Look at the color. Hy should be clear and colorless. And the IG should be clear and colorless, or it
    may be pale yellow. Neither vial should be cloudy or have any particles floating in it.
- Vials need be at room temperature for infusion, which could take up to 60 minutes after removing them from the refrigerator. Do not apply heat or place in microwave. Do not put them back into the refrigerator once they have come to room temperature.
- Do not shake your vials.



#### **Gather your supplies**



In addition to everything that came in your specialty pharmacy kit, you'll need:

- Alcohol swabs
- Antibacterial cleaner
- Soap
- Tape and bandages

#### Wash hands and sanitize work area



The first thing you'll need is a clean work area. Sanitize your work area with an antibacterial cleaner, and if you have an infusion mat, lay it out.



Wash your hands with antibacterial soap, and you're ready to go. If instructed by your doctor, put gloves on when your hands are dry.



Open your supplies. Keep them in their packages and place near the clean work area.



# Prepare the hyaluronidase, or Hy

Draw Hy into syringes	10-11
Fill needle set	10

#### **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.

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



#### **Draw Hy into syringes**



To start to prepare the Hy, take the cap off of the dual-vial unit(s). Without shaking the vials, clean each one by wiping it with an alcohol swab. Give it a few seconds to dry.



Next, remove a sterile syringe from the package, and attach it to the needle or needle-less transfer device. Pull back on the plunger to fill the syringe with air. The amount of air should equal the amount of Hy in the vial.

#### **Draw Hy into syringes (continued)**



The next step is to insert the needle or needle-less transfer device into the center of the Hy vial stopper at a 90-degree angle, and push the air into the vial.



Now, turn the vial upside down, and pull back on the plunger to withdraw all of the Hy into the syringe. Remove the needle from the Hy vial and carefully recap it. For any additional vials that you're using, repeat these steps, using a new needle or needle-less transfer device for each vial to collect all of the Hy into a single syringe.

#### Fill needle set



Once you've got your full dose of Hy transferred into the syringe, hold the syringe upright and tap it to remove any air bubbles. Slowly push the plunger until the Hy reaches the tip of the barrel.



Now you're going to attach the subcutaneous needle set. Remove the sterile cap. Attach the needle set to the Hy syringe.



Slowly push the plunger to fill the needle set tubing, stopping when the Hy reaches the needle hub. Lay the syringe down on the clean work surface. Clamp the needle set tubing.



# Prepare the immune globulin, or IG

#### **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 HyQvia, stop the infusion immediately and contact your HCP or call emergency services:

- 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.

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



#### Transfer IG into pooling bag



First, clean each vial of IG by wiping the stopper with an alcohol swab. Give it a few seconds to dry. Be careful not to shake the vials.



Next, remove the pooling bag from its packaging and close off all of the white clamps on the tubes. Make sure the tubing is tightly connected to the port on the pooling bag.



Now, remove the cap from the spike on the gravity fill set.



Insert the spike straight down into the center of the IG vial stopper at a 90-degree angle. The tip of the spike should be all the way inside the stopper.



Turn the IG vial upside down. Unclamp the gravity fill set tubing.

continued on next page

#### **Transfer IG into pooling bag (continued)**



Continue to hold the IG vial upside down. Open the vent on the spike to transfer the IG into the pooling bag. You may need to tap the gravity fill set to float air bubbles to the top of the vial.



Gently wiggle the spike back and forth to make sure you transfer all of the IG. Then, close the clamp and the vent on the gravity fill set tubing. Repeat steps for each additional IG vial needed to achieve your prescribed dose.



When you've finished with your last vial, hold the gravity fill set tubing upright. Open the clamp and tap the gravity fill set tubing to get the last drops of IG into the pooling bag.

#### Attach pump tubing to pooling bag



Next, you need to detach the gravity fill set from the pooling bag, re-cap the end of the fill port, and close the clamp on the fill port.



Use two hands to close the clamp on the pump tubing.



Remove the cap from the administration port on the pooling bag.



Remove the cap from the spike on the pump tubing. Set down the cap, but continue to hold the spike.



Insert the spike into the administration port on the pooling bag.



With a twisting motion, insert the pump tubing into the pump and fill the pump tubing per the pump manufacturer's guide.

Good job! You're ready for hy4.



### Infuse

Insert and secure needle(s)	18
Infuse Hy manually (first)	19
Infuse IG with pump (second)	20

#### **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 HyQvia, stop the infusion immediately and contact your HCP or call emergency services:

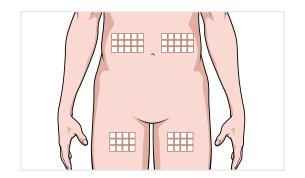
- Brown or red urine, fast heart rate, yellow skin or eyes. These could be signs of a liver or blood problem.
- Chest pain or trouble breathing, blue lips or extremities. These could be signs of a serious heart or lung problem.
- Fever over 100°F. This could be a sign of an infection.

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





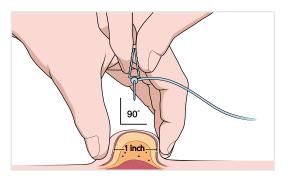
#### Insert and secure needle(s)



Start by choosing an infusion site (or sites). You have two choices—you can infuse in either thigh or either side of your middle to upper abdomen. Remember to rotate your sites for each infusion. You want to avoid bony areas, visible blood vessels, scars, and any areas that are inflamed, irritated, or infected.



If needed, wash your hands with antibacterial soap. Wipe each infusion site with a sterile alcohol wipe (beginning at the center of the site and moving outward in a circular motion) and let dry (at least 30 seconds).



Next, remove the needle cap and firmly grasp and pinch at least 1 inch of skin. Insert the needle with a rapid motion straight into the skin at a 90-degree angle. Secure the needle in place with sterile tape. Repeat this step for additional infusion sites.

#### Infuse Hy manually (first)



Open the clamp on the needle set and gently pull back on the syringe plunger. Look for blood return in the tubing. If blood is seen in the tubing, remove and discard the needle and start at a new site with a new subcutaneous needle. If there's no blood, secure the needle set by applying a sterile, clear dressing over the site. If more than one infusion site is used, you'll follow these steps to check for proper needle placement in both sites at the same time.



Administer the Hy at a rate of 1 to 2 mL per minute per infusion site and increase as tolerated. Divide the contents equally between sites, if more than one site is used.



When all the Hy has been infused, detach the syringe from the needle set, but don't remove the subcutaneous needle(s) from your infusion site(s) because you're going to attach the same needle set to the pump tubing. Remove the sterile cap on the pump tubing that is filled with IG, and attach it to the same needle set.

#### Infuse IG with pump (second)



Now, open the clamp on the pump tubing, and start the pump to begin infusing IG. Make sure to set the pump to infuse at the rates prescribed by your doctor. Begin the IG infusion **right after** the Hy infusion is complete (within 10 minutes). When the IG infusion is complete, if directed by your healthcare professional, flush any remaining IG from the pump tubing with saline to ensure that you receive your full dose.

Good job! You're ready for hy5.



## Finish up

Remove needle(s) and log infusion in your Wellness Journal ......22

#### **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

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

**HyQvia** 





#### Remove needle(s) and log infusion in your Wellness Journal



Start by loosening the clear dressing and pulling the subcutaneous needle wings straight up and out. Place a bandage over the infusion site, and then dispose of the needle set in the sharps container. Check with your specialty pharmacy to learn how to dispose of your sharps container.



Now, you'll want to record your infusion experience and details in your Wellness Journal. You can write in the details of lot number and expiration date or peel the label off your IG vial and place it in the journal.

Follow up with your doctor as directed or if you have any questions or concerns.

Due to the volume that can be infused, swelling is common with HyQvia. Mild to moderate local infusion-site reactions (e.g., swelling and redness) are common side effects of facilitated subcutaneous treatment with HyQvia. Contact your healthcare professional if you have any local reactions or other side effects that bother you or don't go away.



## Congratulations – you did it!

Your infusion is complete! Take a deep breath, let it out, and let those antibodies go to work.

Remember, this guide is not only for learning to infuse, but also can be referred back to at any point to review the specifics of infusing. Don't forget, you've got resources available to you. If you have any questions about HyQvia, write them down in your Wellness Journal and talk to your doctor, visit <a href="https://hyqvia.com">https://hyqvia.com</a>, or reach out to a nurse at your specialty pharmacy.

It's normal to experience some infusion site reactions after your infusion. Talk to your healthcare professional about any side effects that bother you or that don't go away.

#### **IMPORTANT SAFETY INFORMATION (continued)**

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

The most common side effects of HyQvia are:

Headache
 Fatigue
 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, including Warning about Blood Clots, click for Information For Patients, and discuss with your HCP.

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#### What is HvQvia?

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 HvQvia?

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- 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.
- 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 HvQvia.

#### 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 HvQvia.

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

Tell your HCP if you:

- Have or had any kidney, liver, or heart problems or history of blood clots because HvQvia 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 HvQvia can harm the unborn baby or breastfed infant.

#### What are the possible or reasonably likely side effects of HvQvia?

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

#### IMPORTANT SAFETY INFORMATION (continued)

- 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.
- 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 HvQvia 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 HvQvia are:

Headache
 Fatigue
 Nausea
 Fever
 Vomiting

Antibodies to the hyaluronidase component of HvQvia 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.



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