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

HYQVIA administration systems

Considerations for selecting an infusion pump and other ancillary devices

INDICATION AND LIMITATION OF USE

HYQVIA® [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] Solution is indicated for the treatment of primary immunodeficiency (PI) in adults. HYQVIA is for subcutaneous use only. Safety and efficacy of chronic use of Recombinant Human Hyaluronidase in HYQVIA have not been established in conditions other than PI.

IMPORTANT SAFETY INFORMATION

WARNING: THROMBOSIS

- **Thrombosis may occur with immune globulin (IG) products, including HYQVIA. Risk factors may include advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.**
- **For patients at risk of thrombosis, administer HYQVIA at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration.**
- **Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk of hyperviscosity.**

Please see additional Important Safety Information throughout and click here for Full Prescribing Information.

HyQvia = HY+Ig

HY=recombinant human hyaluronidase.
Ig=immune globulin infusion 10% (human).

Takeda does not prefer, recommend, or attest to using any specific infusion pump or other ancillary devices with HYQVIA.

IMPORTANT SAFETY INFORMATION (continued)

Contraindications

- History of anaphylactic or severe systemic hypersensitivity reactions to human IG
- IgA-deficient patients with antibodies to IgA and a history of hypersensitivity to human IG
- Known systemic hypersensitivity to hyaluronidase including Recombinant Human Hyaluronidase of HYQVIA
- Known systemic hypersensitivity to human albumin (in the hyaluronidase solution)

Warnings and Precautions

Hypersensitivity: Severe hypersensitivity reactions may occur, even in patients who have tolerated previous treatment with human IG. If a hypersensitivity reaction occurs, discontinue infusion immediately and institute appropriate treatment. IgA-deficient patients with antibodies to IgA are at greater risk of developing potentially severe hypersensitivity reactions, including anaphylaxis.

Please see additional Important Safety Information throughout and click here for Full Prescribing Information, including Boxed Warning regarding Thrombosis.

Introduction to HYQVIA administration systems

Overview

This booklet is intended to assist healthcare professionals and pharmacies in selecting appropriate equipment for infusing HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] Solution in an office setting or for patient self-administration at home after adequate training.

HYQVIA is administered at high infusion rates of up to 300 mL/h per infusion site.[1] To help provide a positive infusion experience for your patients, the infusion rates and other characteristics of HYQVIA administration should be taken into consideration.

If you have any questions about HYQVIA administration, contact a Takeda representative.

Administration sequence

When administering HYQVIA, the HY component is infused first, followed immediately (within 10 minutes) by infusion of the Ig component through the same needle(s) into the same infusion site(s). If 2 infusion sites are used, the full dose of each component should be divided equally for administration between sites. During the initial ramp-up period, gradually increased infusion rates are used to administer HYQVIA. If the patient tolerates the infusions at the full dose and maximum rate, both the time intervals and number of rate changes of the ramp-up used for successive infusions may be adjusted at the discretion of the physician and patient.[1]

The 2 components of HYQVIA can be administered using one of the following options[1]:

Peristaltic infusion pump	Syringe driver pump
HY component infused by manual syringe push	HY component infused by manual syringe push or by syringe driver pump
Ig component infused by peristaltic infusion pump	Ig component infused by syringe driver pump

Note that Takeda does not prefer, recommend, or attest to using any specific infusion pump or other ancillary devices with HYQVIA.

Depending on which administration system option is used, certain equipment features need to be considered to help facilitate a positive infusion experience for your patients.

The information above provides a general overview of administration. Please click here for the complete Dosage and Administration instructions in the Full Prescribing Information.

HYQVIA pump considerations*

When selecting and preparing a pump for administering HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] Solution, the following criteria should be taken into consideration:

- The Ig component of HYQVIA must be administered using an infusion pump capable of infusing a patient's dose up to every 4 weeks and at an infusion rate of up to 300 mL/h/site[1]
- The selected pump should be indicated for subcutaneous (SC) use[1]
- The pump must have the ability to titrate the flow rate up or down, as required to improve tolerability, while part of a fully assembled administration system[1]
- The pump's maximum occlusion alarm setting should be at least 11.6 psi[2]

Confirmation of appropriate settings for pumps

- Ensure that the pump can be programmed to infuse HYQVIA at the maximum flow rate prescribed for the patient[1]
- Ensure that the downstream occlusion alarm setting is configured to the maximum or highest setting[2]

Actions to take if an occlusion alarm occurs

- Check for kinks in the pump tubing[3]
- Check that the occlusion alarm is set to its maximum[3]
- Check that the SC needle set is 24 gauge and labeled for high flow rates (or low resistance)[1]
- Check that the pump is on the list of pumps that meet criteria (see summary at right)
- If the occlusion alarm persists, reduce the flow rate to complete the HYQVIA infusion

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

Thrombosis: May occur following treatment with IG products and in the absence of known risk factors. In patients at risk, administer at the minimum dose and infusion rate practicable. Ensure adequate hydration before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

Immunogenicity of Recombinant Human Hyaluronidase (rHuPH20): Non-neutralizing antibodies to the Recombinant Human Hyaluronidase component can develop. The clinical significance of these antibodies or whether they interfere with fertilization in humans is unknown.

Please see additional Important Safety Information throughout and click here for Full Prescribing Information, including Boxed Warning regarding Thrombosis.

Pumps that meet criteria†

Summary of pumps that meet the requirements to infuse HYQVIA.

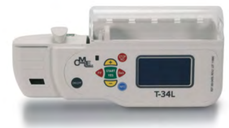
Aitecs
SP-12S PRO[4]
Syringe Driver

- Occlusion alarm pressure‡: Up to 13.1 ± 2.9 psi
- Flow rate accuracy: ± 2%

B. Braun
PERFUSOR Space 2nd Generation[5]
Syringe Driver

- Occlusion alarm pressure: Up to 17.4 psi
- Flow rate accuracy: ± 2%

CME
T34L[6]
Syringe Driver

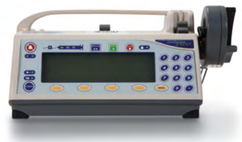


- Occlusion alarm pressure: Up to 29 psi
- Flow rate accuracy: ± 2%

ICU Medical
Plum 360[7]
Syringe Driver

- Occlusion alarm pressure: Up to 15 psi
- Flow rate accuracy: ± 5%

Smiths Medical
MEDFUSION 3500[8]
Syringe Driver



- Occlusion alarm pressure: Up to 16 psi
- Flow rate accuracy: ± 2%

B. Braun
Vista Basic[3]
Peristaltic

- Occlusion alarm pressure: Up to ~17 psi
- Flow rate accuracy: ± 5%

Baxter
SIGMA Spectrum[9]
Peristaltic

- Occlusion alarm pressure: Up to 19 ± 9 psi
- Flow rate accuracy: ± 5%

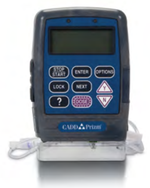
Moog Medical
Curlin 4000 CMS[10]
Peristaltic

- Occlusion alarm pressure: Up to 18 psi
- Flow rate accuracy: ± 6%

Moog Medical
Curlin 6000 CMS[11]
Peristaltic

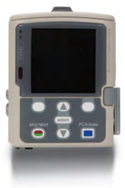
- Occlusion alarm pressure: Up to 18 psi
- Flow rate accuracy: ± 5%

Smiths Medical
CADD-PRIZM VIP[12]
Peristaltic



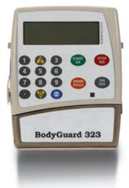
- Occlusion alarm pressure: Up to 18 ± 9 psi
- Flow rate accuracy: ± 6%

Smiths Medical
CADD-Solis VIP[13]
Peristaltic



- Occlusion alarm pressure: Up to 18 ± 9 psi
- Flow rate accuracy: ± 6%

CME
BodyGuard 323[14]
Peristaltic



- Occlusion alarm pressure: Up to 21 psi
- Flow rate accuracy: ± 5%

***This is intended to provide guidance to healthcare professionals when selecting a pump for patients to use to administer HYQVIA. However, this list is not exhaustive. Takeda does not prefer, recommend, or attest to using any specific infusion pump or other ancillary devices with HYQVIA. Follow each infusion pump's manufacturer guidelines before use and administration.**

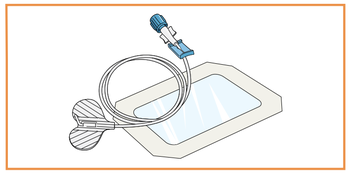
†Flow rate accuracy will vary based on the flow rate, viscosity of solution, temperature during administration, and choice of components.[4]

‡Occlusion alarm pressure is based on the high pressure setting.

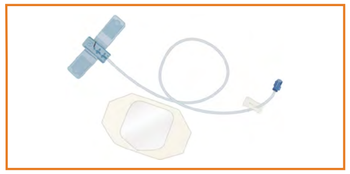
SC needle set considerations

To achieve the maximum flow rate (up to 300 mL/h/site)[1] for HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] Solution, consider the following:

- Use an SC needle set that is 24 gauge and labeled for high flow rates (or low resistance)[1]
- Reminder, both the HY and Ig components of HYQVIA are administered using the same needle set[1]
- Needles are available as single or bifurcated; there are also Y connectors available to allow 2 sites to be infused simultaneously[15,16]
- The needle is positioned at a 90° angle[15,16]



FlowEase SC needle set with a clear dressing



RMS SC needle set with a clear dressing

Commercially available high flow (low resistance) needle sets that can properly administer HYQVIA are shown in the table below.

Name	Needle gauge	Needle length*	Product codes
FlowEase Subcutaneous Infusion Set†[15]	24 gauge	6 mm 9 mm 12 mm	1M2006 1M2009 1M2012
RMS HIgH-Flo Subcutaneous Safety Needle Sets Single Needle Set‡[16]	24 gauge	6 mm 9 mm 12 mm 14 mm	RMS12406 RMS12409 RMS12412 RMS12414
RMS HIgH-Flo Subcutaneous Safety Needle Sets Bifurcated Set[16]	24 gauge	6 mm 9 mm 12 mm 14 mm	RMS22406 RMS22409 RMS22412 RMS22414

*Subcutaneous tissue varies substantially by certain characteristics, such as body site, body mass index, and gender.[17] Clinical judgment and patient assessment during first infusions must be used to identify the best needle length for each patient.

†For more information about FlowEase Subcutaneous Infusion Sets, please call Takeda BioScience Customer Service at 800-423-2090.

‡For more information about RMS HIgH-Flo Subcutaneous Safety Needle Sets, please call RMS Medical Products at 800-624-9600.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

Aseptic Meningitis Syndrome: Has been reported with use of IG and may occur more frequently in females. Conduct a thorough neurological exam on patients exhibiting signs and symptoms, to rule out other causes of meningitis. Discontinuing IG treatment has resulted in remission within several days without sequelae.

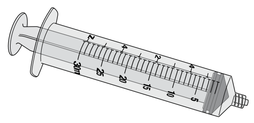
Please see additional Important Safety Information throughout and click here for Full Prescribing Information, including Boxed Warning regarding Thrombosis.

Syringe considerations[1]

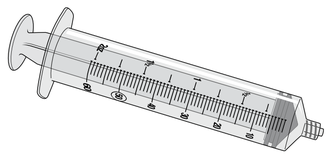
If the administration system chosen for the patient's infusion of HYQVIA involves syringes, then syringes appropriate for the dose volumes and compatible with any syringe driver pump being used should be supplied and available for the infusion.

HYQVIA component	Syringe considerations
HY	Small volume syringe (up to 30 mL) or large volume syringe (up to 60 mL)
Ig	Large volume syringe (up to 60 mL)

The appropriate number of sterile tip caps should also be supplied and available for the infusion. Supply one sterile tip cap per syringe.



Small volume syringe

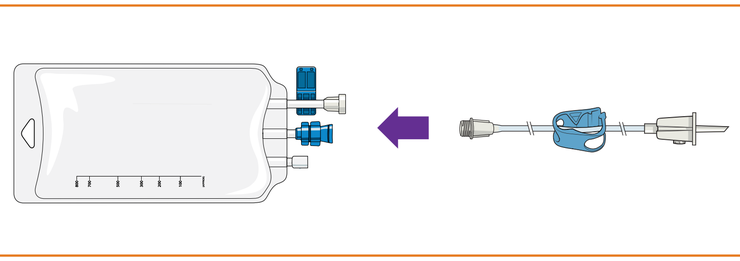


Large volume syringe

Sterile tip caps

Pooling bag considerations[1]

If the administration system chosen for the patient's infusion of HYQVIA involves a pooling bag, then a pooling bag appropriate for the dose volumes and compatible with any peristaltic infusion pump being used should be supplied and available for the infusion.



Single-lead pooling bag

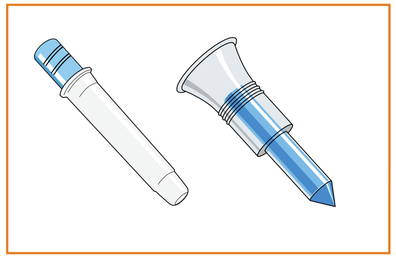
The information above provides a general overview of administration. Please click here for the complete Dosage and Administration instructions in the Full Prescribing Information.

Vial access device considerations[1]

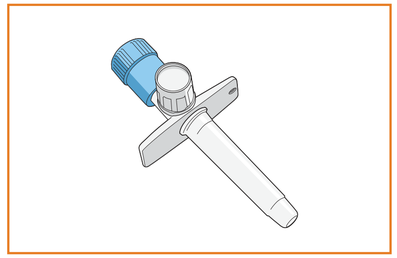
Vial access devices are used to transfer each component of HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] Solution from vials into syringes or a pooling bag. The table below summarizes which devices are appropriate for use with the HY and Ig components.

HYQVIA component	Vial access device type
HY	Needle or needle-less transfer device
Ig	Vented spike

If a patient's full dose requires the use of multiple vials of HYQVIA, then the corresponding quantity of appropriate vial access devices should be supplied and available for the infusion. No vial access device should be reused with a subsequent vial.



Needle or needle-less transfer device



Vented spike

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

Hemolysis: HYQVIA contains blood group antibodies which may cause a positive direct antiglobulin reaction and hemolysis. Monitor patients for signs and symptoms of hemolysis and delayed hemolytic anemia and, if present, perform appropriate confirmatory lab testing.

Renal Dysfunction/Failure: Acute renal dysfunction/failure, acute tubular necrosis, proximal tubular nephropathy, osmotic nephrosis and death may occur with intravenous (IV) use of IG products, especially those containing sucrose. Ensure patients are not volume depleted prior to infusion. In patients at risk due to pre-existing renal insufficiency or predisposition to acute renal failure, assess renal function before initiation and throughout treatment, and consider lower, more frequent dosing. If renal function deteriorates, consider discontinuation.

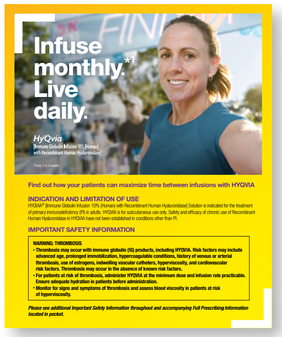
Spread of Localized Infection: Do not infuse HYQVIA into or around an infected area due to potential risk of spreading a localized infection.

Please see additional Important Safety Information throughout and click here for Full Prescribing Information, including Boxed Warning regarding Thrombosis.

Additional information

For additional information about how to infuse HYQVIA, refer to the following resources.

HCP Brochure



HYQVIA Administration Videos

For access to these resources and more, please talk to your Takeda sales representative or visit **HYQVIAhcp.com**.

If you have any questions about HYQVIA administration, contact a Takeda representative.

Infusion pump and needle set customer service phone numbers

If you have questions about an infusion pump or needle set listed in this guide, please refer to the respective manufacturer's guide or contact the customer service number listed below.

Aitecs	+370-5-277-6745	**CME**	+800-323-575-00
B. Braun	800-227-2862	**ICU Medical**	800-241-4002
Baxter	800-356-3454	**Moog Medical**	800-970-2337
Takeda	800-423-2090	**RMS Medical**	800-624-9600
		Smiths Medical	800-258-5361

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INDICATION AND LIMITATION OF USE

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IMPORTANT SAFETY INFORMATION

WARNING: THROMBOSIS

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- **For patients at risk of thrombosis, administer HYQVIA at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration.**
- **Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk of hyperviscosity.**

Contraindications

- History of anaphylactic or severe systemic hypersensitivity reactions to human IG
- IgA-deficient patients with antibodies to IgA and a history of hypersensitivity to human IG
- Known systemic hypersensitivity to hyaluronidase including Recombinant Human Hyaluronidase of HYQVIA
- Known systemic hypersensitivity to human albumin (in the hyaluronidase solution)

Warnings and Precautions

Hypersensitivity: Severe hypersensitivity reactions may occur, even in patients who have tolerated previous treatment with human IG. If a hypersensitivity reaction occurs, discontinue infusion immediately and institute appropriate treatment. IgA-deficient patients with antibodies to IgA are at greater risk of developing potentially severe hypersensitivity reactions, including anaphylaxis.

Thrombosis: May occur following treatment with IG products and in the absence of known risk factors. In patients at risk, administer at the minimum dose and infusion rate practicable. Ensure adequate hydration before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

Immunogenicity of Recombinant Human Hyaluronidase (rHuPH20): Non-neutralizing antibodies to the Recombinant Human Hyaluronidase component can develop. The clinical significance of these antibodies or whether they interfere with fertilization in humans is unknown.

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Please see additional Important Safety Information throughout and click here for Full Prescribing Information.

Warnings and Precautions (continued)

Renal Dysfunction/Failure: Acute renal dysfunction/failure, acute tubular necrosis, proximal tubular nephropathy, osmotic nephrosis and death may occur with intravenous (IV) use of IG products, especially those containing sucrose. Ensure patients are not volume depleted prior to infusion. In patients at risk due to pre-existing renal insufficiency or predisposition to acute renal failure, assess renal function before initiation and throughout treatment, and consider lower, more frequent dosing. If renal function deteriorates, consider discontinuation.

Spread of Localized Infection: Do not infuse HYQVIA into or around an infected area due to potential risk of spreading a localized infection.

Transfusion-Related Acute Lung Injury: Non-cardiogenic pulmonary edema may occur with IV administered IG. Monitor patients for pulmonary adverse reactions. If suspected, perform appropriate tests for presence of anti-neutrophil and anti-HLA antibodies in both product and patient serum. May be managed using oxygen therapy with adequate ventilatory support.

Transmittable Infectious Agents: Because HYQVIA is made from human plasma, it may carry a risk of transmitting infectious agents (e.g. viruses, other pathogens). No cases of transmission of viral diseases or variant Creutzfeldt-Jakob disease (vCJD) have been associated with HYQVIA.

Interference with Lab Tests: False positive serological test results and certain assay readings, with the potential for misleading interpretation, may occur as the result of passively transferred antibodies.

Adverse Reactions

The most common adverse reactions observed in >5% of patients in the clinical trials were: local adverse reactions including pain, erythema, edema, and pruritus, and systemic adverse reactions including, headache, antibody formation against Recombinant Human Hyaluronidase (rHuPH20), fatigue, nausea, pyrexia, and vomiting.

Drug Interactions

Passive transfer of antibodies may transiently interfere with the immune responses to live attenuated virus vaccines (e.g., measles, mumps, rubella, and varicella).

Please click here for Full Prescribing Information.

References: 1. HYQVIA [Prescribing Information]. Lexington, MA: Baxalta US Inc. **2.** Data on File. Takeda US Inc. 2019. **3.** Vista Basic [Instructions for Use]. Revision 950787. Bethlehem, PA: B. Braun Medical Inc; June 2002. **4.** SP-12S PRO [Operator's Manual]. Revision 2.0, version SPP03. Vilnius, Lithuania: Viltechmeda; March 2007. **5.** PERFUSOR Space 2nd Generation [Instructions for Use]. Version 1.3. Bethlehem, PA: B. Braun Medical Inc; March 2010. **6.** T34L Syringe Driver [brochure]. Caesarea Medical Electronics website. http://media.wix.com/ugd/33c51f_39bbfe23c8ef471489f0e833a52767f8.pdf. Accessed October 9, 2019. **7.** Plum 360 Infusion System with ICU Medical MedNet. ICU Medical website. http://ecatalog.icumed.com/infusion-pumps/300100404. Accessed October 10, 2019. **8.** MEDFUSION 3500 Syringe Infusion Pump [Operation Manual]. Revision 3. Duluth, GA: Medex Inc; 2003. **9.** SIGMA Spectrum [Operator's Manual]. Revision C. Medina, NY: SIGMA, LLC; 2011. **10.** Curlin 4000 CMS Ambulatory Infusion System [User's Manual]. Salt Lake City, UT: Moog, Inc; 2004. **11.** Curlin 6000 CMS Ambulatory Infusion System [User's Manual]. Salt Lake City, UT: Moog, Inc; 2004. **12.** CADD-PRIZM VIP Ambulatory Infusion Pump [Technical Manual]. St. Paul, MN: Smiths Medical ASD, Inc; November 2010. **13.** CADD-Solis VIP Ambulatory Infusion Pump [Technical Manual]. St. Paul, MN: Smiths Medical ASD, Inc; 2012. **14.** Caesarea Medical Electronics. Multi therapy solutions. https://pdf.medicalexpo.com/pdf/caesarea-medical-electronics/multi-therapy-solutions/67935-105723-_8.html. Accessed February 11, 2020. **15.** FlowEase [Subcutaneous] Infusion Set [Instructions for Use]. Lexington, MA: Baxalta US Inc. **16.** HIgH-Flo Subcutaneous Safety Needle Sets [Ordering Information]. RMS Medical Products website. http://www.rmsmedicalproducts.com/?node=products&item=hfl&sec=ordering. Accessed October 9, 2019. **17.** Gibney MA, Arce CH, Byron KJ, Hirsch LJ. Skin and subcutaneous adipose layer thickness in adults with diabetes at sites used for insulin injections: implications for needle length recommendations. *Curr Med Res Opin*. 2010;26(6):1519-1530.

Notes

OnePath® is here for your primary immunodeficiency (PI) patients and their caregivers, every step of the way

OnePath offers personalized, dedicated assistance to eligible* PI patients prescribed a Takeda product. This support includes:

- Facilitating an insurance benefits investigation
- Working with various sites of care (eg, hospital-owned specialty pharmacies/ home care, infusion centers) to coordinate treatment access for PI patients
- Directing PI patients and caregivers to educational resources available to them
- Arranging for PI patients and/or their caregivers to receive free, in-home, self-administration training with a specially trained nurse (if applicable)
- Enrolling eligible PI patients in the OnePath Co-Pay Assistance Program or providing information about additional financial assistance options

OnePath offers co-pay assistance to eligible PI patients

Up to 100% of qualified co-pay expenses may be covered*†

For eligible commercially insured OnePath PI patients, our co-pay assistance program covers out-of-pocket expenses related to treatment for which there is a co-pay such as deductibles, coinsurance, and certain infusion charges (if applicable), up to the program maximum.

Patient Support Managers are ready to assist your patients.

Patient Support Managers are available Monday through Friday, 8:30 AM to 8:00 PM ET. Call 1-866-888-0660 for more information or visit OnePath.com.

*At a minimum to be eligible, patients must be enrolled in OnePath and have commercial insurance. Other terms and conditions apply. Contact OnePath for more information.

†IMPORTANT NOTICE: The OnePath 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. Co-payment 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 1-866-888-0660. Coverage of certain administration charges does not apply for patients residing in Massachusetts, Michigan, Minnesota, Rhode Island, and Vermont. Takeda reserves the right to rescind, revoke, or amend the Program at any time without notice.

myIgsource

MyIgSource is an educational resource where your patients can learn more about PI and connect with an individual who is living with PI or has a loved one with PI.

Have your patients connect at MyIgSource.com or call 1-855-250-5111.

Infuse monthly.*
Live daily.

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

*Every 3 or 4 weeks.

Please see additional Important Safety Information throughout and click here for Full Prescribing Information.

Takeda