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

Administration systems

for HyQvia®

Your consideration guide for selecting infusion pumps and ancillary devices for your patients with primary immunodeficiency (PI) or chronic inflammatory demyelinating polyneuropathy (CIDP)

INDICATIONS

HyQvia is indicated for the treatment of primary immunodeficiency (PI) in adults and pediatric patients two years of age and older and for chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy to prevent relapse of neuromuscular disability and impairment in adults. HyQvia is for subcutaneous use only.

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 for Full Prescribing Information.

Introduction to HyQvia administration systems

HyQvia comes in a dual-vial unit—one vial of Immune Globulin Infusion 10% (Human) [IG 10%] and one vial of Recombinant Human Hyaluronidase.[1]

Using the HyQvia administration systems guide

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] at a site of care setting and infusion center, or for patient self-administration at home after adequate training.

The guide can be used for both of the HyQvia indications: primary immunodeficiency (PI) and chronic inflammatory demyelinating polyneuropathy (CIDP).

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 for Full Prescribing Information, including Boxed Warning regarding Thrombosis.

Identifying the patient's administration system

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

Healthcare professionals can work with their patients to determine the number of infusion sites and treatment intervals. These factors, along with number of vials to infuse, may influence the patient's equipment requirements.

Steps to finding the right equipment for patients:

1. Identify treatment indication of patient: PI or CIDP
2. Click the tabs below that correspond with the patient treatment indication
3. Review pumps and other supplies needed to administer HyQvia

Support for you and your patients

Click on the "Resources & index" tab in either the PI or CIDP section to see the range of support and resources available at HyQvia.com, including:

- Brochures to share with your patients
- Step-by-step infusion videos
- Patient starter kits

The gray "Additional resources" tab has information on two support programs:

- MyIgSource—resources and support to empower people to live a better life with PI
- Takeda Patient Support—helping patients with PI or CIDP gain access to their prescribed Takeda medication

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

Thrombosis: Has been reported to occur following treatment with IG products, including HyQvia 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 click for the complete Dosage and Administration instructions in the Full Prescribing Information.

PI: Peristaltic pump & pooling bag | **PI:** Syringe driver pump | **PI:** Resources & index | **CIDP:** Peristaltic pump & pooling bag | **CIDP:** Resources & index | Additional resources

PI: Peristaltic pump and pooling bag

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

Considerations for selecting a peristaltic pump for use with HyQvia*

- The IG component of HyQvia must be administered using an infusion pump capable of infusing a patient's dose up to every 2,3, or 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]
- While part of the full assembled administration system, the pump must have the ability to titrate the flow rate up or down, as required to improve tolerability[1]
- The pump's maximum occlusion alarm setting should be at least 11.6 psi[2]
- A vented pump tubing set is necessary if infusing directly from the vial

A range of peristaltic pumps* meet the criteria† to administer HyQvia

Moog Medical Curlin 4000 CMS[3]

- Occlusion alarm pressure: Up to 18 psi
- Flow rate accuracy: ± 6%
- Flow rate: 0.1-400 mL/hr
- Delivery rate mode: variable

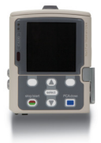
Moog Medical Curlin 6000 CMS[4]

- Occlusion alarm pressure: Up to 18 ± 3 psi
- Flow rate accuracy: ± 5%
- Flow rate: 0.1-400 mL/hr
- Delivery rate mode: variable

Smiths Medical CADD-Prizm VIP[5]

- Occlusion alarm pressure: Up to 18 ± 9 psi
- Flow rate accuracy: ± 6%
  - 0.1 for values between 0.1 and 100
- Flow rate: 0-350 mL/hr
- Delivery rate mode: intermittent

Smiths Medical CADD-Solis VIP[6]



- Occlusion alarm pressure: Up to 18 ± 9 psi
- Flow rate accuracy: ± 6%
- Flow rate: 0.1-500 mL/hr
- Delivery rate mode: variable, step delivery option

B. Braun Vista Basic[7]

- Occlusion alarm pressure: Up to ~17 psi
- Flow rate accuracy: ± 5%
- Flow rate: 0.1-800 mL/hr
- Delivery rate mode: variable

Eitan–Q Core Sapphire Multi-Therapy[8]

- Occlusion alarm pressure: Up to 17.4 psi
- Flow rate accuracy: ± 2.5%
- Flow rate: 0.1-999 mL/hr
- Delivery rate mode: multi-therapy

***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.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

Aseptic Meningitis Syndrome: Has been reported with use of IG, including HyQvia and may occur more frequently in females. The syndrome usually begins within several hours to two days following IG treatment.

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 for Full Prescribing Information, including Boxed Warning regarding Thrombosis.

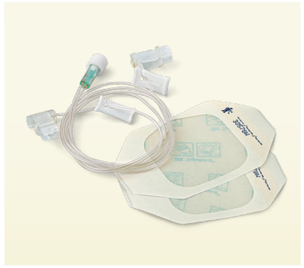
SC needle sets

To achieve the maximum flow rate (up to 300 mL/h/site)[1] for HyQvia, 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 two sites to be infused simultaneously[9,10]
- The needle is positioned at a 90° angle[9,10]

FlowEase SC needle set with a clear dressing

SC needle set with a clear dressing



Bifurcated needle with two site dressings

Select from commercially available high-flow (low-resistance) needle sets that can properly administer HyQvia

Name	Needle gauge	Needle length‡	Product codes
Baxter FlowEase Subcutaneous Infusion Set§[9]	24 gauge	6 mm 9 mm 12 mm	1M2006 1M2009 1M2012
Koru HIgH-Flo Subcutaneous Safety Needle Sets Single Needle Set[10]	24 gauge	6 mm 9 mm 12 mm 14 mm	RMS12406 RMS12409 RMS12412 RMS12414
Koru HIgH-Flo Subcutaneous Safety Needle Sets Bifurcated Set[10]	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.[11] 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 1-800-423-2090.

Please click for the complete Dosage and Administration instructions in the Full Prescribing Information.

PI: Ancillary supplies required for use with peristaltic pump and pooling bag

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

Syringe[1]

If the administration system chosen for the patient's infusion of HyQvia involves syringes, then syringes appropriate for the dose volume should be supplied.

HyQvia component	Syringe considerations
Hy	Small volume syringe (up to 30 mL) or large volume syringe (up to 50 mL)
IG	Large volume syringe (up to 50 mL)

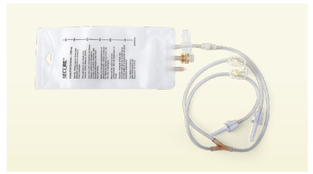
Small volume syringe

Large volume syringe

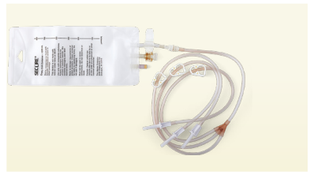
Pooling bag[1]

If the administration system chosen for the patient's infusion of HyQvia involves a pooling bag, then a non-vented administration set will be required. The administration set is a dedicated set for the specific pump. Patients may be given pooling bags with up to 3 legs.

Single-leg pooling bag



Two-leg pooling bag with vented spikes



Three-leg pooling bag with vented spikes

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.

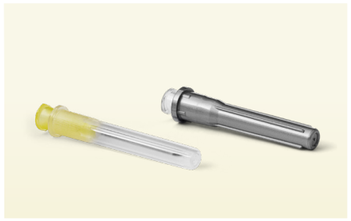
Please see additional Important Safety Information throughout and click for Full Prescribing Information, including Boxed Warning regarding Thrombosis.

Vial access device[1]

Vial access devices are used to transfer each component of HyQvia 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	Syringe considerations
Hy	Needle (18-22 gauge) or needleless transfer device
IG	Needle (18-22 gauge) or 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. No vial access device should be reused with a subsequent vial.



Needle or needleless transfer device

Be sure to include a Patient Starter Kit when filling a patient's first prescription. See page 12 for details.

Please click for the complete Dosage and Administration instructions in the Full Prescribing Information.

PI: Syringe driver pump

Considerations for selecting a syringe driver pump for HyQvia*

- The IG component of HyQvia must be administered using an infusion pump capable of infusing a patient's dose up to every 3-4 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]
- While part of the full assembled administration system, the pump must have the ability to titrate the flow rate up or down, as required to improve tolerability[1]
- The pump's maximum occlusion alarm setting should be at least 11.6 psi[2]

A range of syringe driver pumps meet the criteria to administer HyQvia*†

Aitecs SP-12S Pro[12]

- Occlusion alarm pressure†:Up to 13.1 ± 2.9 psi
- Flow rate accuracy: ± 2%
- Flow rate: 0.1-1500 mL/hr
- Delivery rate mode: continuous

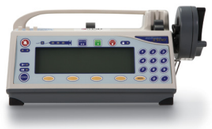
B. Braun Perfusor Space 2nd Generation[13]

- Occlusion alarm pressure: Up to 17.4 psi
- Flow rate accuracy: ± 2%
- Flow rate: 0.01-999.9 mL/hr
- Delivery rate mode: continuous

ICU Medical Plum 360[14]

- Occlusion alarm pressure: Up to 15 psi
- Flow rate accuracy: ± 5%
- Flow rate: 0.5-500 mL/hr
- Delivery rate mode: continuous

Smiths Medical Medfusion 3500[15]



- Occlusion alarm pressure: Up to 16 psi
- Flow rate accuracy: ± 2%
- Flow rate: 0.01 mL/hr-1130 mL/hr
- Delivery rate mode: continuous

***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.

Please click for the complete Dosage and Administration instructions in the Full Prescribing Information.

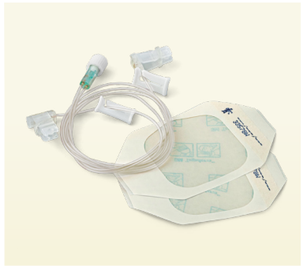
SC needle sets

To achieve the maximum flow rate (up to 300 mL/h/site)[1] for HyQvia, 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[9,10]
- The needle is positioned at a 90° angle[9,10]

FlowEase SC needle set with a clear dressing

SC needle set with a clear dressing



Bifurcated needle with two site dressings

IMPORTANT SAFETY INFORMATION (continued)

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.

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

PI: Ancillary supplies required for use with syringe driver pump

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

Syringe[1]

If a syringe driver pump is the administration system chosen for the patient's infusion of HyQvia, then syringes appropriate for the selected syringe driver pump should be supplied.

HyQvia component	Syringe considerations
Hy	Small volume syringe (up to 30 mL) or large volume syringe (up to 50 mL)
IG	Large volume syringe (up to 50 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 cap

Vial access device[1]

Vial access devices are used to transfer each component of HyQvia from vials into syringes. The table below summarizes which devices are appropriate for use with the Hy and IG components.

HyQvia component	Vial access device type
Hy	Needle (18-22 gauge) or needleless transfer device
IG	Needle (18-22 gauge) or 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. No vial access device should be reused with a subsequent vial.

Needle or needleless transfer device

Vented spike

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

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.

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

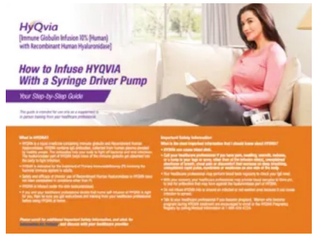
Be sure to include a Patient Starter Kit when filling a patient's first prescription. See page 12 for details.

Please click for the complete Dosage and Administration instructions in the Full Prescribing Information.

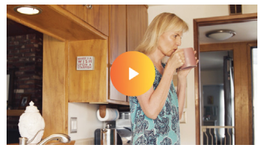
PI: Additional resources

Patients can visit the PI patient website to access a range of support and resources. The brochures and videos below are a few of the resources they'll find.

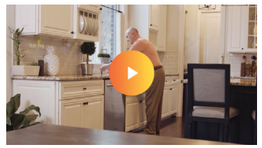
Patient brochures

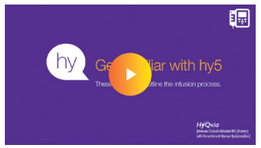


Infusion videos



Real patients Mary and Michael share their infusion experiences





Step-by-step infusion video with peristaltic pump

If you have any questions about HyQvia, contact your Takeda representative or visit HyQviaHCP.com.

Patient Starter Kit

Takeda has provided Patient Starter Kits to your organization to send to patients along with their infusion system. It includes information about HyQvia and the supplies they will receive, a step-by-step infusion guide, an infusion mat, and a wellness journal to record and track their infusions.

IMPORTANT SAFETY INFORMATION (continued)

Adverse Reactions

The most common adverse reactions observed in >5% of patients in the clinical trials were:

Primary Immunodeficiency (PI): 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.

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

PI: Index of pumps

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

Peristaltic pumps by manufacturer

Syringe driver pumps by manufacturer

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

B. Braun 1-800-227-2862

Eitan Medical 1-877-541-9944

ICU Medical 1-800-241-4002

Koru Medical 1-800-624-9600

Moog Medical 1-800-970-2337

Smiths Medical 1-800-258-5361

CIDP: Peristaltic pump and pooling bag

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

Considerations for selecting a peristaltic pump for use with HyQvia*

- The IG component of HyQvia must be administered using an infusion pump capable of infusing a patient's dose every 2, 3, or 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]
- While part of the full assembled administration system, the pump must have the ability to titrate the flow rate up or down, as required to improve tolerability[1]
- The pump's maximum occlusion alarm setting should be at least 11.6 psi[2]
- A vented pump tubing set is necessary if infusing directly from the vial

A range of peristaltic pumps* meet the criteria† to administer HyQvia

Moog Medical Curlin 4000 CMS[3]

- Occlusion alarm pressure: Up to 18 psi
- Flow rate accuracy: ± 6%
- Flow rate: 0.1-400 mL/hr
- Delivery rate mode: variable

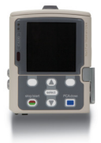
Moog Medical Curlin 6000 CMS[4]

- Occlusion alarm pressure: Up to 18 ± 3 psi
- Flow rate accuracy: ± 5%
- Flow rate: 0.1-400 mL/hr
- Delivery rate mode: variable

Smiths Medical CADD-Prizm VIP[5]

- Occlusion alarm pressure: Up to 18 ± 9 psi
- Flow rate accuracy: ± 6%
  - 0.1 for values between 0.1 and 100
- Flow rate: 0-350 mL/hr
- Delivery rate mode: intermittent

Smiths Medical CADD-Solis VIP[6]



- Occlusion alarm pressure: Up to ~17 psi
- Flow rate accuracy: ± 5%
- Flow rate: 0.1-800 mL/hr
- Delivery rate mode: variable

B. Braun Vista Basic[7]

- Occlusion alarm pressure: Up to ~17 psi
- Flow rate accuracy: ± 5%
- Flow rate: 0.1-800 mL/hr
- Delivery rate mode: variable

Eitan–Q Core Sapphire Multi-Therapy[8]

- Occlusion alarm pressure: Up to 17.4 psi
- Flow rate accuracy: ± 2.5%
- Flow rate: 0.1-999 mL/hr
- Delivery rate mode: multi-therapy

***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.

IMPORTANT SAFETY INFORMATION (continued)

Adverse Reactions (continued)

The most common adverse reactions observed in >5% of patients in the clinical trials were:

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP): local reactions, headache, pyrexia, nausea, fatigue, erythema, pruritus, increased lipase, abdominal pain, back pain, and pain in extremity.

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

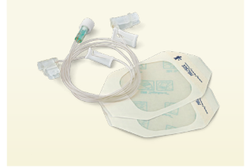
SC needle sets

To achieve the maximum flow rate (up to 300 mL/h/site)[1] for HyQvia, consider the following:

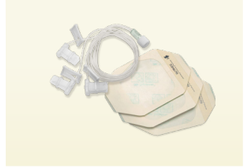
- Use an SC needle set that is 24 gauge and labeled for high flow rates (or low resistance)[1]
- Reminder, both the Hy and IG components of HyQvia are administered using the same needle set[1]
- Needles are available as single, bifurcated, or trifurcated; there are also Y connectors available to allow two sites to be infused simultaneously[9,10]
- The needle is positioned at a 90° angle[9,10]

FlowEase SC needle set with a clear dressing

SC needle set with a clear dressing



Bifurcated needle with two site dressings



Trifurcated needle set

Select from commercially available high-flow (low-resistance) needle sets that can properly administer HyQvia

Name	Needle gauge	Needle length‡	Product codes
Baxter FlowEase Subcutaneous Infusion Set§[9]	24 gauge	6 mm 9 mm 12 mm	1M2006 1M2009 1M2012
Koru HIgH-Flo Subcutaneous Safety Needle Sets Single Needle Set[10]	24 gauge	6 mm 9 mm 12 mm 14 mm	RMS12406 RMS12409 RMS12412 RMS12414
Koru HIgH-Flo Subcutaneous Safety Needle Sets Bifurcated Set[10]	24 gauge	6 mm 9 mm 12 mm 14 mm	RMS22406 RMS22409 RMS22412 RMS22414
Koru HIgH-Flo Subcutaneous Safety Needle Sets 3-Needle Set[10]	24 gauge	6 mm 9 mm 12 mm 14 mm	RMS32406 RMS32409 RMS32412 RMS32414

‡Subcutaneous tissue varies substantially by certain characteristics, such as body site, body mass index, and gender.[11] 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 1-800-423-2090.

Please click for the complete Dosage and Administration instructions in the Full Prescribing Information.

CIDP: Ancillary supplies required for use with peristaltic pump and pooling bag

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

Syringe[1]

If the administration system chosen for the patient's infusion of HyQvia involves syringes, then syringes appropriate for the dose volume should be supplied.

HyQvia component	Syringe considerations
Hy	Small volume syringe (up to 30 mL) or large volume syringe (up to 50 mL)
IG	Large volume syringe (up to 50 mL)

Small volume syringe

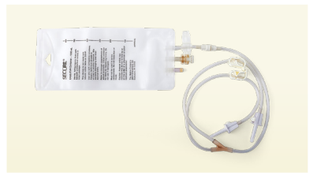
Large volume syringe

5 mL syringe
(to check for blood return in infusion tubing)

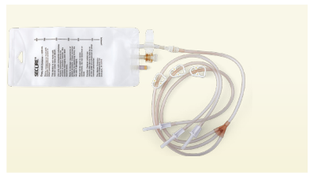
Pooling bag[1]

If the administration system chosen for the patient's infusion of HyQvia involves a pooling bag, then a non-vented administration set will be required. The administration set is a dedicated set for the specific pump. Patients may be given pooling bags with up to 3 legs.

Single-leg pooling bag



Two-leg pooling bag with vented spikes



Three-leg pooling bag with vented spikes

IMPORTANT SAFETY INFORMATION (continued)

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).

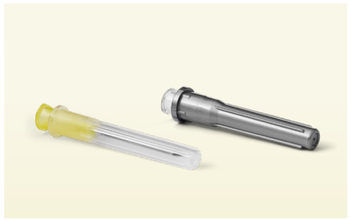
Please see additional Important Safety Information throughout and click for Full Prescribing Information, including Boxed Warning regarding Thrombosis.

Vial access device[1]

Vial access devices are used to transfer each component of HyQvia 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	Syringe considerations
Hy	Needle (18-22 gauge) or needleless transfer device
IG	Needle (18-22 gauge) or 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. No vial access device should be reused with a subsequent vial.



Needle or needleless transfer device

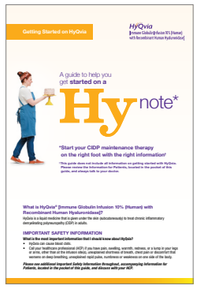
The CIDP Patient Starter Kit can be ordered from HyQvia patient website at HyQvia.com/starterkit-cidp. See page 18 for details.

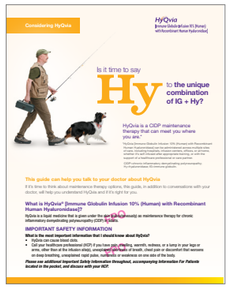
Please click for the complete Dosage and Administration instructions in the Full Prescribing Information.

CIDP: Additional resources

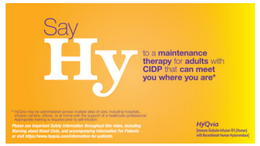
Patients can visit the CIDP patient website to access a range of support and resources. The brochures and videos below are a few of the resources they'll find.

Patient brochures





Infusion videos



If you have any questions about HyQvia, contact your Takeda representative or visit HyQviaHCP.com.

Patient Starter Kit

Patient Starter Kits, which can be ordered online at HyQvia.com/StarterKit-CIDP, include information about HyQvia and the supplies patients will receive, a step-by-step infusion guide, an infusion mat, and a wellness journal to record and track their infusion.

IMPORTANT SAFETY INFORMATION (continued)

Use in Specific Populations

Pregnancy: Limited human data are available on the use of HyQvia during pregnancy. The effects of antibodies to the Recombinant Human Hyaluronidase on the human embryo or fetal development are unknown. It is not known whether HyQvia can cause fetal harm when administered to a pregnant woman or if it can affect reproductive capacity. HyQvia should be given to a pregnant woman only if clearly needed.

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

CIDP: Index of pumps

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

Peristaltic pumps

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.

B. Braun 1-800-227-2862

Eitan Medical 1-877-541-9944

Koru Medical 1-800-624-9600

Moog Medical 1-800-970-2337

Smiths Medical 1-800-258-5361

Notes

Additional resources

my Ig source

For over 10 years, MyIgSource has brought education, community, and support together as an integrated resource designed by and for people with PI. MyIgSource offers many ways to connect and engage, including live events, a robust and active online community, one-on-one calls with the IG Community Support Team, and more. MyIgSource—empowering people to live a better life with PI.

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

Takeda Patient Support

Welcome to Takeda Patient Support

When your patient enrolls, we're here to help them gain access to their prescribed Takeda medication. Our dedicated specialists provide several services, including:

- **Benefits investigation** to help determine your patient's insurance benefits
- **Prior authorization** (PA), reauthorization, and appeals information in coordination with your patient's insurance company to determine any requirements
- **Financial assistance options** including the Takeda Patient Support Co-Pay Assistance Program. The program may cover up to 100% of your patient's out-of-pocket co-pay costs, if they're eligible*†
- **Education and training** about their prescribed Takeda treatment or condition from nursing professionals. Our nurses cannot provide medical advice
- **Specialty pharmacy triage**, coordination, and more‡

Need Assistance?

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

Need to enroll your patient?

Visit our convenient online enrollment portal at **TakedaPatientSupport.com/hcp**.

You can also enroll your patient by faxing the completed Start Form to **1-866-861-1752**.

If English is not your patient's preferred language, we can assist them in a language of their choosing.

*Must meet eligibility requirements.

†**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 patient's insurance provider. If your patient's insurance situation changes, they 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.

‡If your patients' medication is dispensed by specialty pharmacy.

INDICATIONS

HyQvia is indicated for the treatment of primary immunodeficiency (PI) in adults and pediatric patients two years of age and older and for chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy to prevent relapse of neuromuscular disability and impairment in adults. HyQvia is for subcutaneous use only.

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.**

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: Has been reported to occur following treatment with IG products, including HyQvia 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.

Aseptic Meningitis Syndrome: Has been reported with use of IG, including HyQvia and may occur more frequently in females. The syndrome usually begins within several hours to two days following IG treatment.

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.

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.

Warnings and Precautions (continued)

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:

Primary Immunodeficiency (PI): 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.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP): local reactions, headache, pyrexia, nausea, fatigue, erythema, pruritus, increased lipase, abdominal pain, back pain, and pain in extremity.

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).

Use in Specific Populations

Pregnancy: Limited human data are available on the use of HyQvia during pregnancy. The effects of antibodies to the Recombinant Human Hyaluronidase on the human embryo or fetal development are unknown. It is not known whether HyQvia can cause fetal harm when administered to a pregnant woman or if it can affect reproductive capacity. HyQvia should be given to a pregnant woman only if clearly needed.

Please click for Full Prescribing Information.

References: 1. HyQvia. Prescribing Information. Takeda Pharmaceuticals U.S.A., Inc.; 2024. **2.** Data on File. Takeda US Inc; 2019. **3.** Curlin 4000 CMS Ambulatory Infusion System. User's Manual. Moog, Inc; 2004. **4.** Curlin 6000 CMS Ambulatory Infusion System. User's Manual. Moog, Inc; 2004. **5.** CADD-PRIZM VIP Ambulatory Infusion Pump. Technical Manual. Smiths Medical ASD, Inc; November 2010. **6.** CADD-Solis VIP Ambulatory Infusion Pump. Technical Manual. Smiths Medical ASD, Inc; 2012. **7.** Vista Basic. Instructions for Use. Revision 950787. B. Braun Medical Inc; June 2002. **8.** Sapphire Multi-therapy and Dedicated Infusion Pumps. User Manual. Rev. 15. Eitan Group and Q Core Medical Ltd; 2019. **9.** FlowEase [Subcutaneous] Infusion Set. Instructions for Use. Lexington, MA: Baxalta US Inc. **10.** HIgH-Flo Subcutaneous Safety Needle Sets. Ordering Information. RMS Medical Products website. Accessed March 29, 2022. https://www.korumedical.com/ **11.** 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. **12.** SP-12S PRO. Operator's Manual. Revision 2.0, version SPP03. Viltechmeda; March 2007. **13.** PERFUSOR Space 2nd Generation. Instructions for Use. Version 1.3. B. Braun Medical Inc; March 2010. **14.** Plum 360 Infusion System with ICU Medical MedNet. ICU Medical website. Accessed March 29, 2022. http://ecatalog.icumed.com/infusion-pumps/300100404 **15.** MEDFUSION 3500 Syringe Infusion Pump. Operation Manual. Revision 3. Medex Inc; 2003.

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

If you are looking for additional information about HyQvia, contact your Takeda sales representative or visit HyQviaHCP.com

Frequently asked questions

Who should I contact if I have a question about an infusion pump or needle set in this guide?

You should contact the manufacturer. Please see page 13 for a list of pump manufacturers' phone numbers.

Who should I contact if I have questions about HyQvia administration?

Please contact Takeda Medical Information at 1-877-TAKEDA-7 (1-877-825-3327).

What if my patients need help paying for out-of-pocket costs?

The Takeda Patient Support Co-Pay Assistance Program can cover up to 100% of patients' out-of-pocket co-pay costs, if they're eligible. See page 21 for full eligibility requirements.

Scan QR code or click here to see which specialty pharmacy providers are authorized to dispense HyQvia.

IMPORTANT SAFETY INFORMATION

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

US-HYQ-0670v1.0 02/24

Takeda