Nexviazyme®
(avalglucosidase alfa)

IMMUNOTESTING SERVICES HCP GUIDE

NEXVIAZYME (AVALGLUCOSIDASE ALFA)

Guidance for healthcare professionals on immunology testing services provided with Nexviazyme administration

▼ This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

MAT-AU-2200917. Date of preparation: March 2023.

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1 OBJECTIVES AND GOALS

Nexviazyme (avalglucosidase alfa) treatment should be supervised by a physician experienced in the management of patients with Pompe disease or other inherited metabolic or neuromuscular diseases.

The Nexviazyme Immunotesting Services Guide is part of the educational materials provided to physicians involved in managing patients with Pompe disease treated with Nexviazyme. Treating physicians may make this material available to other healthcare professionals (HCPs) involved in the management of the disease as required. The main purposes of the Immunotesting Service Guide are to:

1. Guide HCPs to carry out immunological testing which will help to further characterise the potential mechanism of infusion-associated reactions (IARs) and hypersensitivity reactions, and appropriately manage patients experiencing loss of treatment response due to anti-drug antibodies (ADAs).
2. Provide information on Sanofi's Rare Disease Specialty Testing services, for immunological testing practicalities.

2 KEY CONTACTS

- To report an adverse event(s) (AE) occurring in association with the use of Nexviazyme:

  Please contact the Pharmacovigilance Team at Sanofi:

  E-mail: ae@sanofi.com
  Phone: (02) 8666 2123

- For information on how to access Sanofi's Rare Disease Specialty Testing services or other test-related questions for Nexviazyme:

  Please contact Sanofi Medical Information:

  E-mail: MedInfo.Australia@sanofi.com
  Phone: 1800 818 806

- For medical information regarding Pompe Disease or Nexviazyme:

  Please contact Sanofi Medical Information:

  E-mail: MedInfo.Australia@sanofi.com
  Phone: 1800 818 806

3 TESTING RECOMMENDATIONS

The testing service described in this HCP guide is part of Sanofi's Rare Disease Specialty Testing service provided through LabCorp. It provides a complimentary offer of testing: anti-drug IgG antibody, adverse event related immunogenicity testing and biomarker testing services for patients with Pompe Disease and other rare diseases. This is a service offered to HCPs which can also be managed through a local laboratory for some of the testing.

Testing recommendations for Nexviazyme:

- Baseline serum sample collection prior to the first infusion is strongly encouraged.
- IgG antibody titres should be regularly monitored, and IgG ADA testing should be considered if patients do not respond as expected to therapy.
- Treated patients may be tested for ADAs if they experience a decrease in clinical benefit despite continued treatment with Nexviazyme.
- AE-driven immunologic testing, including IgG and IgE ADA, should also be considered in patients who experience moderate/severe or recurrent IARs suggestive of hypersensitivity reactions, anaphylactic reactions.
- AE-driven immunologic testing may be considered for patients at risk for allergic reaction or previous anaphylactic reaction to Myozyme (alglucosidase alfa).

Please see Sections 4.4 and 4.8 of the Product Information (PI) for more information related to Nexviazyme immunogenicity.

4 TESTING PRACTICALITIES

4.1 DESCRIPTION OF THE IMMUNOTESTING SERVICES

A list of the immunogenicity testing offered (free of charge) with Nexviazyme treatment through the Sanofi's Rare Disease Specialty Testing service with Labcorp is provided in **Table 1**. Detailed sample collection and submission information will be provided upon account set-up with LabCorp.

Table 1 - Clinical immunology testing characteristics

TEST	INDICATION FOR TESTING	SAMPLE TYPE	FREQUENCY	COLLECTION TIME[a]
IgG	Routine monitoring	Serum-Frozen	Routine monitoring	Sample should be pre-infusion or ≥3 days post infusion
IgG/ inhibitory antibody	Decreased response to treatment or lack of effect	Serum-Frozen	Ad hoc (as needed)	Sample should be pre-infusion or ≥3 days post infusion
IgG/IgE antibody	Moderate/severe or recurrent IARs suggestive of hypersensitivity reactions, anaphylactic reactions	Serum-Frozen	Ad hoc (as needed)	Pre-infusion or at least ≥3 days post infusion
Serum tryptase	Moderate/severe or recurrent IARs suggestive of hypersensitivity reactions, anaphylactic reactions	Serum-Frozen	Ad hoc (as needed)	1 to 3 hours post infusion reaction
Complement activation	Moderate/severe or recurrent IARs suggestive of hypersensitivity reactions, anaphylactic reactions	EDTA Plasma-Frozen	Ad hoc (as needed)	1 to 3 hours post infusion reaction

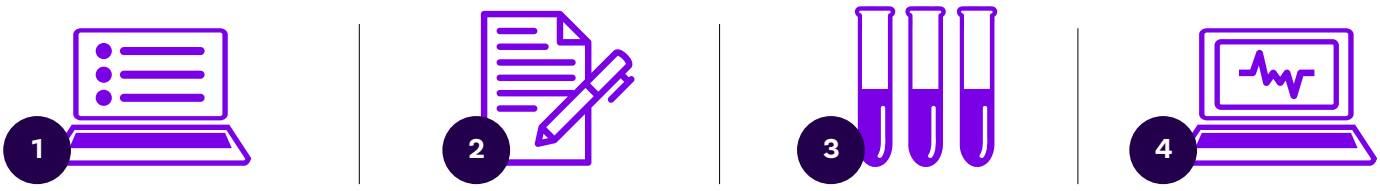
[a] Document the time and date when the sample was taken.

4.2 PROCEDURE TO ACCESS IMMUNOTESTING SERVICES

The procedure described in **Figure 1** applies to all tests performed as part of an adverse event investigation (including IgG antibody, IgE antibody, inhibitory antibody, complement activation), and to all samples for routine IgG monitoring. Please contact your local Sanofi representative or Sanofi Medical Information E-mail: MedInfo.Australia@sanofi.com for further information on how to access Sanofi's Rare Disease Specialty Testing services.

Figure 1 - Procedure to use the Sanofi Rare Diseases Specialty testing services

INSTRUCTIONS FOR PHYSICIANS REQUESTING SPECIALTY DIAGNOSTIC TESTING SERVICES



Enrol with LabCorp - complete account set-up process

Complete a Test Request Form (TRF) and collect an Informed Consent Form (ICF) for each patient

Collect and submit sample(s)

Receive results

5 REPORTING ADVERSE EVENTS

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. HCPs are asked to report any suspected adverse reactions to the TGA at www.tga.gov.au/reporting-problems or to contact Sanofi Pharmacovigilance team. For full contact details on reporting adverse reactions please refer to Section 2 Key Contacts.

Rare Disease Specialty Testing Program

Account Setup Form **Click here to complete the account setup process online.**

Facility Details

Facility Name: _____ Facility Phone (include country code):_____

Facility Postal (Street) Address: _____ Town/City: _____

State/Province: _____ Postal Code: _____ Country: _____

Facility Contact Name:_____ Facility Contact Email Address: _____

If the facility is a reference laboratory that will report to its ordering clinician(s), please provide the full name of the Laboratory Director.

Laboratory Director Name _____

Otherwise, please provide the full names of the ordering clinicians below.

Clinician Name: _____ Clinician Name: _____

Clinician Name: _____ Clinician Name: _____

Testing (Please check the type that may be ordered)

○ Anti-Drug IgG Antibody ○ Adverse Event Hypersensitivity ○ Adverse Event Neutralizing Antibody ○ Biomarkers

Sample Submission Details

Other than the location previously provided, are there other locations where Marken will pick up samples for this program?

_____

_____

_____

_____

Results (Please select your preferred method for result delivery)

○ Autofax (provide fax number including country code): _____

○ Labcorp Link online portal (please provide names and email addresses for any Labcorp Link users that require setup)

_____ / _____

_____ / _____

Please allow 7 - 10 business days from receipt of a completed form for account setup. Please send the completed form directly to Labcorp through email to RareDiseaseProgram@Labcorp.com or fax to +1-855-224-0889.

Contact Labcorp with any questions regarding account setup through email at RareDiseaseProgram@Labcorp.com.

By creating an account, I certify that we are not listed on any sanctions list published by the U.S. Departments of Commerce, Treasury, or State, including, but not limited to, the Specially Designated Nationals and Blocked Persons List and the Denied Persons List.

The information you provide on this form will be used to create the Labcorp account under which testing services for the Sanofi Genzyme Specialty Rare Disease Testing Program will be placed and results delivered. You have a right to access, rectify or have your personal data deleted and you have the right to withdraw your consent at any time. In order to exercise this right, or if you have any questions, please contact our Privacy Officer by e-mail at privacyofficer@labcorp.com. Labcorp's privacy policy can be found by visiting: https://www.labcorp.com/hipaa-privacy.

Facility Contact Signature: _____ **Date:** _____

Required

sanofi-aventis australia pty ltd trading as Sanofi ABN 31 008 558 807.
Talavera Corporate Centre, Building D, 12-24 Talavera Road, Macquarie Park, NSW 2113.
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Nexviazyme®
(avalglucosidase alfa)

HOME INFUSION HCP GUIDE

NEXVIAZYME (AVALGLUCOSIDASE ALFA)

This guide is not intended to suggest or recommend home infusion therapy for any patient. The decision to use home infusion therapy is made by the treating physician, who knows the patient's current clinical status and previous infusion history, in consultation with the patient. This guide is solely to share information that might be helpful to healthcare professionals and their patients when treated via home infusion therapy.

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1 OBJECTIVES AND GOALS

The main objective of this document is to provide guidance to healthcare professionals (HCPs) for the management of patients receiving Nexviazyme® at home to mitigate the important risks "medication errors in home infusion setting" and "infusion associated reactions including hypersensitivity and anaphylactic reactions with or without development of IgG and IgE antibodies."

Enzyme replacement therapy (ERT) is available for some of the lysosomal storage disorders. Nexviazyme infusion therapy is available for the treatment of patients one year of age and older with Pompe disease and is generally well tolerated. Home administration by a trained healthcare professional may be considered for individual patients after safety and tolerability have been established in the clinical setting.

The decision to transfer Nexviazyme infusion to the patient's home setting is made by the treating physician and should consider patient preferences and medical status.

The home infusion will take place under the responsibility of the treating physician. It is the responsibility of the treating physician to ensure safe administration by trying to avoid risks of medication errors and reduce and mitigate the risk of IARs, in particular hypersensitivity reactions. This should be checked and documented by the treating physician.

The processes presented in this document serve as overall guidance but are subject to local medical practice and national rules and regulations.

2 REQUIREMENTS AND ORGANISATION OF HOME INFUSION

The treating physician is responsible for referring a suitable patient for home infusion and needs to agree upon the home infusion procedure.

Once the patient has been considered eligible for home infusion based on the Australian Product Information (PI) for Nexviazyme, a set of requirements must be considered to ensure that Nexviazyme infusions can be safely, efficiently, and reliably delivered at the patient's home. The level of support required from the infusion nurse in the home setting will be discussed and agreed by the treating physician and the patient and/or caregiver(s).

In principle, the initial instructions and training of the infusion nurse will be given in the hospital. The infusion nurse will carry out the entire procedure for the infusions at the patient's home.

2.1 PATIENT

2.1.1 General

- **The patient and/or caregiver(s) have been informed by the treating physician about the treatment to be provided at home, the associated risks (including hypersensitivity reactions and medication errors),** the provision of medical assistance at home, and must agree to the treatment at home.
- **The patient and/or caregiver(s) understand the illness and can recognise adverse events including hypersensitivity reactions** and understand the procedure to be followed should these occur.
- **The home environment must be conducive to home infusion therapy,** including a clean environment with electricity, water, telephone access, refrigeration, and physical space to support storage of Nexviazyme and other infusion supplies.
- The patient has been informed that the infusion should always be administered in the presence of an adult, i.e. the infusion nurse is adequately trained on how to handle infusion associated reactions (IARs) and medication errors and/or a caregiver.

2.1.2 Medical Status

- The patient must be **physically and mentally able** to undergo the infusions at home. The treating physician is responsible for the recommendation to receive Nexviazyme infusions at home.
- The patient has **venous access or a central venous access device** that allows adequate infusion.

2.2 TREATING PHYSICIAN

The treating physician is responsible for the initiation of all necessary administrative actions which will allow the other parties involved (patient and/or caregiver(s), infusion nurse, pharmacy) to proceed.

- **The treating physician is responsible for selection of the infusion rate and dose.** The infusion rate of Nexviazyme that was tolerated by the patient in a more controlled setting (e.g., in the hospital or in another appropriate setting of outpatient care) must not be changed in the home setting, unless medically warranted at the discretion of the treating physician.

- **The home infusion will take place under the responsibility of the treating physician.** It is the responsibility of the treating physician to ensure safe administration to the patient in order to avoid risks of medication errors and reduce/mitigate the risk of IARs, in particular hypersensitivity reactions.
- **Pre-infusion treatment**, if administered in the hospital or another appropriate setting of outpatient care (e.g. antihistamines, paracetamol, ibuprofen, corticosteroids), **must be provided based on the patient-specific prescription.** This treatment must not be altered in the home setting unless medically warranted at the discretion of the treating physician.
- The treating physician must ensure that a rapid and reliable line of communication is available to expedite an emergency response in case immediate medical attention is required.
- **Emergency treatment must be available and provided** based on the patient-specific prescription and should be described in a Logbook or equivalent.
- **Adverse events experienced by the patient need to be reported to the treating physician or his/her medical designate immediately.** Subsequent infusions may need to occur in a hospital or in another appropriate setting of outpatient care until no such adverse reaction is present at the discretion of the treating physician or his/her medical designate.
- **Regular disease monitoring** of the home-infused patient is the responsibility of the treating physician.
- **Appropriate scheduling and monitoring of the infusions** is the responsibility of the treating physician and infusion nurse.

2.3 PHARMACY AND INFUSION EQUIPMENT

Treatment and all necessary equipment will be provided according to local arrangements and regulations.

2.4 INFUSION NURSE

The infusion nurse will have a coordinating role with the treating physician and the patient and/or caregiver(s) in organising the treatment at home, and will establish with the treating physician, patient and/or caregiver(s) the level of support necessary in the home.

- The infusion nurse is qualified to give IV infusions, has been appropriately trained on the administration of Nexviazyme, and is trained on the possible adverse events (including serious adverse events such as anaphylactoid reactions) and the actions to be taken should they occur.
- **The infusion nurse will strictly follow the prescribed method of preparation and administration** of Nexviazyme, as stated in this guide.
- The infusion nurse will strictly follow the prescribed dose and infusion rate of Nexviazyme, as stated by the treating physician.
- **The infusion nurse records each administration of Nexviazyme** in a Logbook or equivalent.
- Appropriate scheduling and monitoring of the infusions is the responsibility of the treating physician and infusion nurse.
- **Medications must be available to respond to an emergency situation, if necessary. In the event of IAR, the infusion nurse must discontinue the infusion and phone the treating physician and/or emergency number 000. The treating physician and/or emergency number 000 must also be phoned if an IAR occurs shortly after completion of the infusion. Any IAR must be recorded in a Logbook or equivalent for subsequent reporting to the Sponsor by the infusion nurse or the treating physician (see Section 5).**

3 ADMINISTRATION OF NEXVIAZYME

Instructions for use relating to the reconstitution, dilution and administration can be found in the Australian Product Information for Nexviazyme. A detailed description is provided in this section.

3.1 PRESCRIPTION

The Nexviazyme dose, required reconstituted volume, infusion rate, premedication, emergency medication, as well as any changes will be determined by the treating physician. The prescription must be written in a Logbook or equivalent. Any changes of this prescription (dose or infusion rate) must again be reported in a Logbook or equivalent.

3.2 SUPPLIES

Supplies are generally provided by the hospital/pharmacy to the patient or to a third party with the appropriate prescription:

- Vials of Nexviazyme, powder for concentrate for solution for infusion (100 mg per vial); must be stored in a clean refrigerator at a temperature of between +2°C and +8°C.
- Sterile water for injection to reconstitute Nexviazyme (10 ml per vial).
- 5% dextrose in water for IV administration. See **Table 1** for needed volume based on prescribed dose.
- 5% dextrose in water to flush infusion line post-infusion.
- Chlorhexidine 0.5% in alcohol 70% (antiseptic solution).
- Appropriate number of 10 mL, 20 mL and 50 mL syringes depending on dose of Nexviazyme.
- Sterile hypodermic needles (calibre Gauge 20G or 21G). Plan 2 needles per 4 vials.
- In-line low protein-binding 0.2 µm filter.
- Supply for the installation of a peripheral venous path or central venous path according to local guidelines.
- Supply needed for IV infusion according to local guidelines and material required to comply with hygienic and aseptic conditions, as well as waste disposal rules according to local guidelines.
- Pretreatment medication (if applicable).
- Emergency medication.

3.3 PREPARATION

NOTE: The instructions for use (reconstitution, dilution and administration) can be found in the Nexviazyme PI. A detailed description is provided in this section of this guide.

Patients with an acute underlying illness at the time of Nexviazyme infusion appear to be at greater risk for IARs. Thus, the infusion nurse must check the patient medical status before starting the preparation of Nexviazyme.

Before reconstitution, it is also recommended to install the venous pathway (peripheral venous catheter), or to connect the patient's central venous pathway, according to local protocols, to ensure Nexviazyme can be administered immediately after its reconstitution.

- Check the number of vials is appropriate.
- Remove the vials from the refrigerator and set aside for approximately 30 minutes to allow them to reach room temperature.
- Check the expiry date printed on the bottom of the vial pack (do not use Nexviazyme after the labelled expiry date).

3.4 RECONSTITUTION

Aseptic technique should be used during reconstitution.

- Remove the flip-off cap from the Nexviazyme vial.
- Disinfect the rubber stopper of the Nexviazyme vial with chlorhexidine and allow to air dry.
- Open the sterile water for injections.
- Draw the required amount (ml) of sterile water into the syringe.
- Each vial should be reconstituted by slowly injecting 10.0 ml of water for injections (WFI) to each vial. Each vial will yield 100 mg/10 ml (10 mg/ml).
- Avoid forceful impact of the WFI on the powder and foaming. This is performed by slow drop-wise addition of the WFI down the inside of the vial and not directly onto the lyophilised powder.
- Each vial should be tilted and rolled gently to dissolve the lyophilised powder. It should not be inverted, swirled, or shaken.
- Small bubbles may appear after the mixing. Let the solution settle for a few minutes to allow any bubbles present to disappear and to ensure that the powder is properly reconstituted.
- Repeat the process for all Nexviazyme vials. To limit the risk of coring the cap, needles may be changed every 4 vials.
- Immediate visual inspection should be performed on the reconstituted vials for particulate matter and discoloration. If upon immediate inspection particles are observed or if the solution is discoloured, the reconstituted medicinal product should not be used. The solution should be allowed to become dissolved.
- It is recommended that the vials be diluted promptly after reconstitution to minimise protein particle formation over time.

From a microbiological point of view, the reconstituted product should be used immediately. If not used for dilution immediately, in-use storage times and conditions prior to dilution are the responsibility of the user. Reconstituted and diluted products can be stored up to 24 hours at 2-8°C.

3.5 DILUTION

The reconstituted solution should be diluted in 5% dextrose in water to a final concentration of 0.5 mg/ml to 4 mg/ml. See **Table 1** for the recommended total infusion volume based on the patient weight.

- Disinfect the cap/opening of 1 bag of 5% dextrose solution using chlorhexidine and allow to air dry.
- Insert the needle in the cap of the infusion bag and withdraw a volume of 5% dextrose solution, equivalent to the volume of the reconstituted Nexviazyme solution to be added. This corresponds to 1 mL for every 10 mg of prescribed Nexviazyme.
- For example, if the prescribed dose is 1200 mg, the volume of Nexviazyme to be diluted is 1200mg x 10mg/mL = 120 mL. Therefore, 120 mL should be removed from the 5% bag of dextrose solution.
- The reconstituted solution should be added slowly and directly into the 5% dextrose solution. Foaming or agitation of the infusion bag should be avoided. Air introduction into the infusion bag should be avoided.
- Mix the infusion bag solution by gently inverting or massaging the infusion bag. It should not be shaken.

Table 1 - Projected intravenous infusion volumes for Nexviazyme administration by patient weight at 20 and 40 mg/kg dose

Patient weight range (kg)	Total infusion volume for 20 mg/kg (ml)	Total infusion volume for 40 mg/kg (ml)
5.1 to 10	50	100
10.1 to 20	100	200
20.1 to 30	150	300
30.1 to 35	200	400
35.1 to 50	250	500
50.1 to 60	300	600
60.1 to 100	500	1000
100.1 to 120	600	1200
120.1 to 140	700	1400
140.1 to 160	800	1600
160.1 to 180	900	1800
180.1 to 200	1000	2000

From a microbiological point of view, the medicinal product should be used immediately after dilution. If not used immediately, in-use storage times and conditions are the responsibility of the user. Diluted product should not be stored longer than 24 hours at 2-8°C and up to 9 hours (including infusion time) at room temperature (up to 25°C).

3.6 ADMINISTRATION

- Once Nexviazyme has been diluted, attach the tubing to the infusion bag.
- Connect a low protein binding, 0.2 µm in line filter to the infusion bag.
- This step avoids administration of inadvertently introduced particles during IV dose preparation.
- Prime the infusion line with the diluted Nexviazyme via gravity and connect the infusion line to the patient vein path.
- **Before starting the infusion, check the patient's pulse, blood pressure, respiratory rate and temperature.**
- After the infusion is complete, the intravenous line should be flushed with dextrose 5% in water at the same rate and the needle removed.
- Nexviazyme should not be infused in the same intravenous line with other medicinal products.

The Nexviazyme dose, infusion rate, as well as any changes, will be determined by the treating physician. The treatment must not be altered in the home setting, unless medically warranted at the discretion of the treating physician.

4 NEXVIAZYME SAFETY INFORMATION

4.1 RECOGNITION OF ADVERSE DRUG REACTIONS (ADRS)

The most frequently reported adverse drug reactions are infusion associated reactions whether administered at hospital or in another appropriate setting of outpatient care.

An infusion associated reaction (IAR) is defined as any adverse event occurring during the infusion or during the hours following infusion and assessed as potentially causally related to the administration of the product (Nexviazyme). Related events occurring after the post-infusion period may be considered IARs at the discretion of the reporter.

In clinical studies with Nexviazyme, IARs were reported to occur at any time during and/or within a few hours after the infusion of Nexviazyme and were more likely with higher infusion rates.

Hypersensitivity reactions, including anaphylaxis, have also been reported in Nexviazyme-treated patients.

Table 2 illustrates the observed signs and symptoms of IAR/hypersensitivity/anaphylactic reactions. Please refer to Sections 4.4 and 4.8 of the current approved PI for complete information on the safety of Nexviazyme.

Table 2 - Observed signs and symptoms of IARs/hypersensitivity/anaphylactic reactions

System Organ Class	Preferred Term
Respiratory	Respiratory distress Cough Breath sounds abnormal Oxygen saturation decreased
Cardiovascular	Tachycardia Flushing Hypertension
Gastrointestinal	Nausea Diarrhoea Vomiting Lip swelling Swollen tongue
Cutaneous	Erythema Pruritus Rash Urticaria Hyperhidrosis
Nervous system	Dizziness Headache Tremor
General disorders and administration site conditions	Chest discomfort Chills Fatigue Influenza-like illness Pain
Eye	Ocular hyperaemia
Musculoskeletal	Pain in extremity

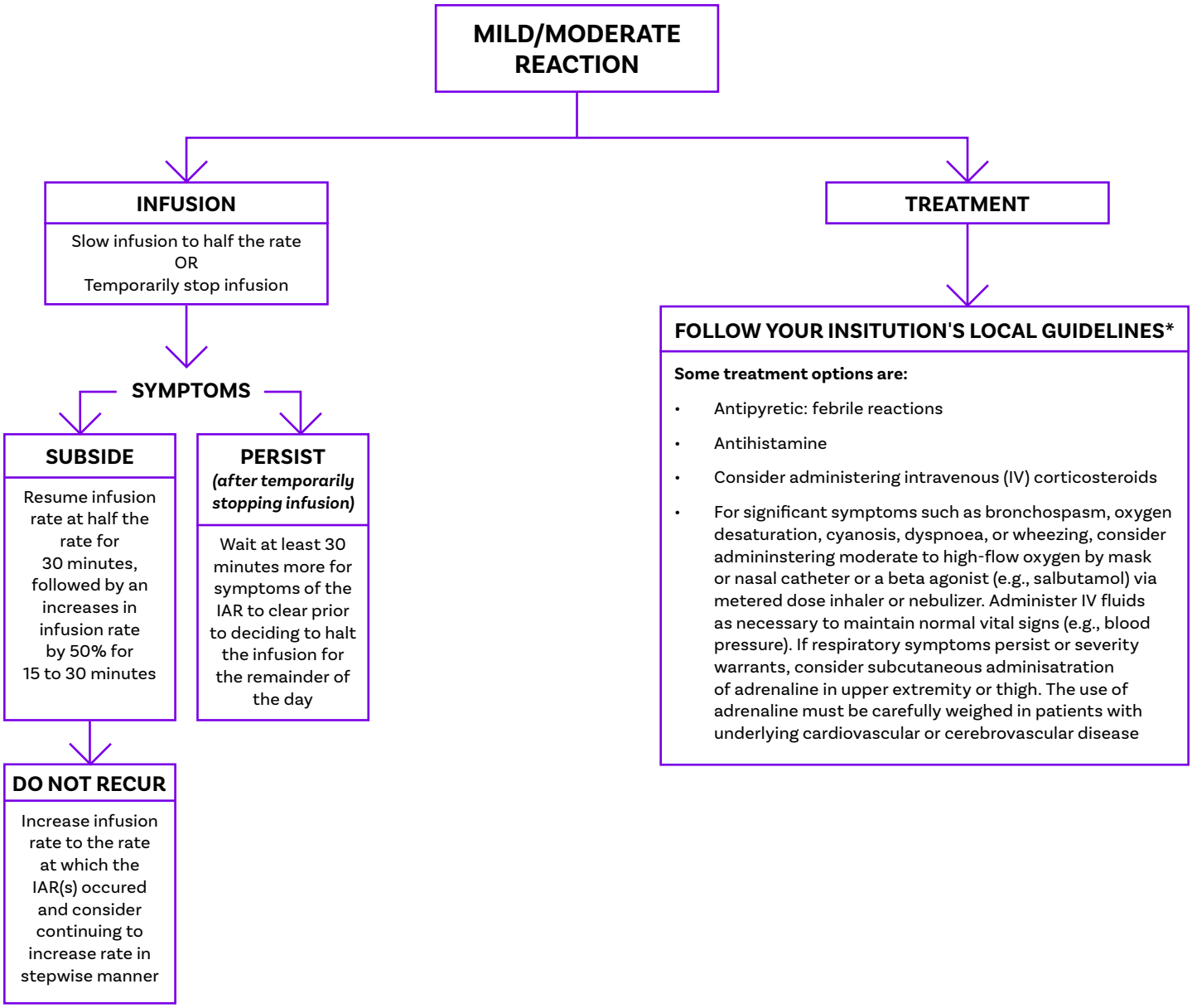
- **Patients with an acute underlying illness at the time of Nexviazyme infusion appear to be at greater risk for IARs.**
- **Patients with advanced Pompe disease may have compromised cardiac and respiratory function, which may predispose them to a higher risk of severe complications from IARs.**
- **Antihistamines, antipyretics, and/or corticosteroids can be given to prevent or reduce IARs. However, IARs may still occur in patients after receiving pre-treatment.**

4.2 CLINICAL MANAGEMENT OF ADVERSE DRUG REACTIONS

The majority of IARs and hypersensitivity reactions were mild or moderate and were managed with standard clinical practices (see Sections 4.4 and 4.8 of Nexviazyme PI for further details).

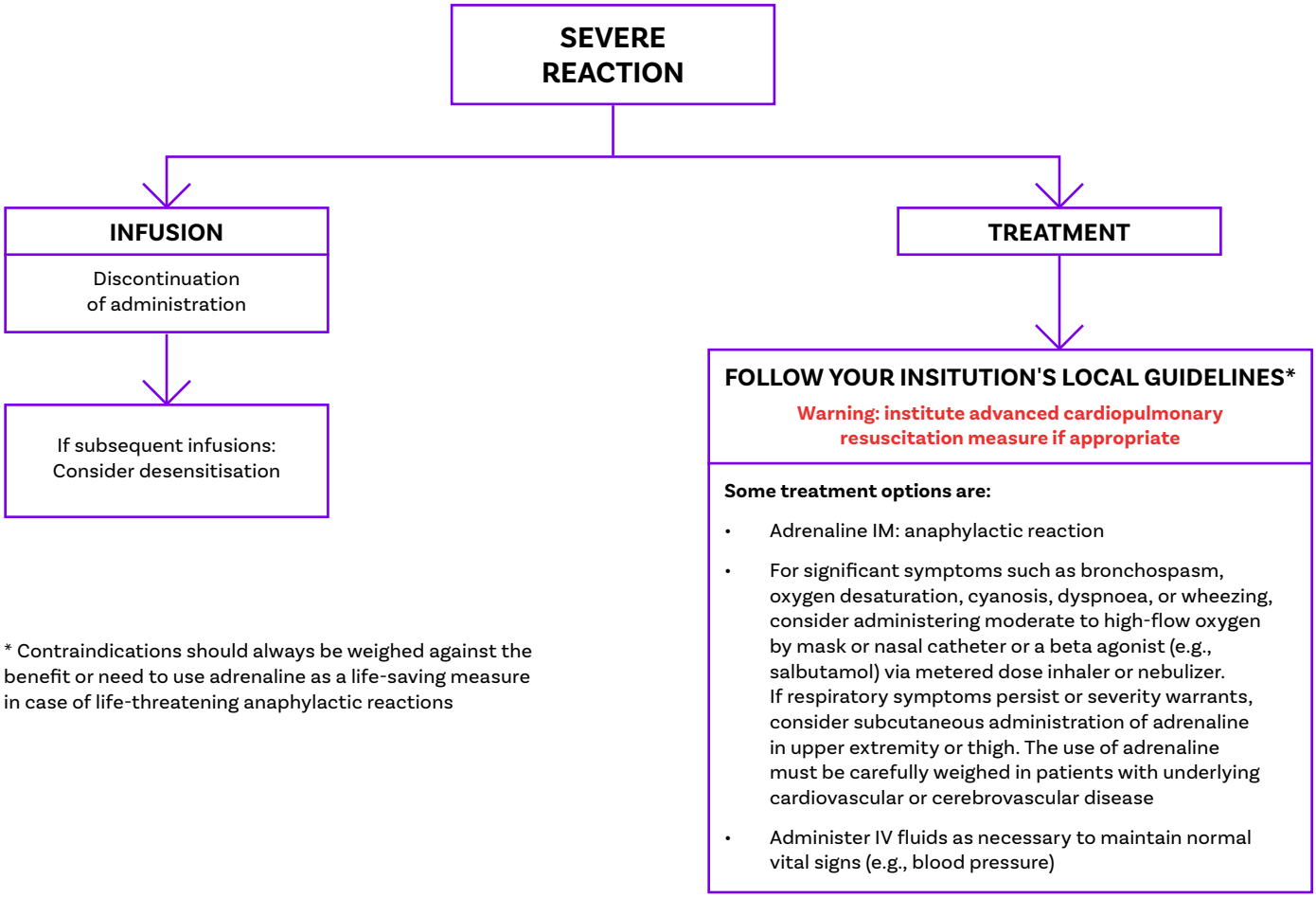
If the patient experiences IAR including hypersensitivity and anaphylactic reactions during the home infusion, the infusion process should be stopped immediately but not removed, and appropriate medical treatment should be initiated if needed. Please see **Figure 1** and **Figure 2** as examples. **Subsequent infusions may need to occur in a hospital or in an appropriate setting of outpatient care until no such adverse reaction is present**. Dose and infusion rate must not be changed without consulting the responsible physician.

Figure 1 - Clinical management of mild to moderate reactions



* Contraindications should always be weighed against the benefit or need to use adrenaline as a life-saving measure in case of life-threatening anaphylactic reactions

Figure 2 - Clinical management of severe reactions



* Contraindications should always be weighed against the benefit or need to use adrenaline as a life-saving measure in case of life-threatening anaphylactic reactions

5 SAFETY REPORTING

An adverse event (AE) is defined as any untoward physical, psychological, or behavioural occurrence in a patient administered a medicinal product which does not necessarily have to have a causal relationship with this treatment. A serious adverse event (SAE) involves an occurrence defined as having at least one of the following outcomes or characteristics:

- Results in death.
- Is life-threatening (any event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe).
- Required in-patient hospitalisation or prolongation of an existing hospitalisation.
- Results in persistent or significant disability/incapacity (any adverse event that resulted in a substantial disruption of a person's ability to conduct normal life functions).
- Is a congenital anomaly/birth defect.
- Is an important medical event (any event that, based upon appropriate medical judgement, may jeopardise the patient and may require medical or surgical intervention to prevent one of the outcomes listed above).

In case of any AEs, please report these to the Sanofi Pharmacovigilance Team at ae@sanofi.com or call (02) 8666 2123. AEs can also be reported directed to the TGA at www.tga.gov.au/reporting-problems.

If a mistake was made in the preparation and/or administration of the drug, the treating physician should be informed to determine appropriate action. Any medication errors should also be reported to Sanofi's Pharmacovigilance Team.

6 FURTHER INFORMATION

Please refer to the Australian PI for complete indication statements and further information about the approved use of Nexviazyme. Other detailed information on Nexviazyme is available at www.ebs.tga.gov.au.