

Document No. 04b

Project Title: NHS National Framework for Natalizumab - February 2024

Offer reference number: CM/PHR/23/5701

Period of framework: 1 February 2024 to 31 August 2025 with an option or options to extend (at the Authority's discretion) for a period or periods up to a total of 24 months.

Assessment Criteria, Stability Protocol and Additional Specification Requirements

Assessment criteria

1. All medicines must conform to the fixed gateway criteria listed in Document No. 07b – Quality Assurance Policy to support the National Contract Procurement of Licensed Medicines v6 (October 2023), Appendix 1. Non-compliance on any single point will result in a Critical Score (refer to 3.3 Document No. 07b).

Medicine packaging should comply to best practice for labelling and packaging to ensure that medicines can be used safely by all patients, the public and healthcare professionals alike. Good practice principles set out in:

- Best practice guidance on the labelling and packaging of medicines (MHRA December 2020)
- Promoting safer use of injectable medicines (NPSA Alert 20, March 2007)
- Design for patient safety: A guide to the graphic design of medication packaging (NPSA 0463A 2008)
- Design for patient safety: A guide to labelling and packaging of injectable medicines (NPSA 2008) ISBN: 978-1-906624-02-6

If unacceptable patient safety risks are identified for which risk mitigation measures are likely to be impracticable or insufficiently effective a critical score will be assigned to the medicine.

2. Please find below a link to the Stability Protocol:



Stability-part-1-small-molecules-5th-Ed-Sep

APPENDIX A**Additional Specification Requirements (supplementary to general and regulatory)**

The NHS has additional requirements to those identified within the general specification. Those requirements are specified within this Appendix A to Document No. 04b – Assessment Criteria, Stability Protocol and Additional Specification Requirements.

Awards for these products will be made, where possible, to offers meeting the additional specification (subject to the offers meeting all other contract award criteria stated in paragraph 11.1 of Document No. 02 – Terms of Offer).

Offers for products that do not meet the additional specification will only be awarded to the framework agreement in the absence of any offers meeting the additional specification (subject to the offers meeting all other award criteria stated in paragraph 11.1 of Document No. 02 – Terms of Offer).

Offerors product information within PharmaQC will be used to determine whether offered products meet the additional requirements where possible. The Product details and pack details recorded (not artwork or photographs) will be used and, in the absence of the relevant fields being completed, it will be deemed that the offered product does not meet the requirement.

1. Packaging protection from light

The NHS requires the following products to be contained in packaging designed to protect the product from light:

N/A

2. Cytotoxic products in blister packs/sachets or with Child Resistant Closure (CRC)

The NHS requires the following cytotoxic products to be contained in a blister pack (or sachet) presentation or have a CRC if the presentation is in a bottle/tub:

N/A

As stated in Document No. 04a Quality Assurance Process, Table 1, a SPC will be required as part of the tender submission on Pharma QC to ensure products are compliant with the presentation requirements stated above.

3. Specific administration requirements

The NHS requires the following product to be licensed for administration both with and without dilution:

N/A

The NHS requires the following product to be licensed for the route(s) of administration to include intrathecal route:

N/A

The NHS requires the following product to be licensed for the route(s) of administration to include Intramuscular and Intravenous:

N/A

4. Oral liquid products to have Child Resistant Closure (CRC)

The NHS requires the following oral liquid products to have a CRC:

N/A

Where no offered product includes a CRC the product should be such that the end-user should be able to apply one if required.

As stated in Document No. 04a Quality Assurance Process, Table 1, a SPC will be required as part of the tender submission on Pharma QC to ensure products are compliant with the presentation requirements stated above.

5. Patient Packs

Where offers are received for tablets or capsules or oral solutions/suspensions which do not represent the tendered pack size but represent a suitable alternative patient pack for dispensing awards will be made to the lowest-priced offered patient pack (subject to the offers meeting all other award criteria stated in criteria stated in paragraph 11.1 of Document No. 02 – Terms of Offer).

6. Additional Specification Requirements

- Sugar free to be defined as being free from fructose, glucose, or sucrose. (see [Guidance on prescribing | Medicines guidance | BNFC | NICE](#))
- The NPC descriptor 'form' may indicate any of the following terms: suspension, oral solution, syrup or elixir. Regardless of the term used, as long as the product is in an oral liquid formulation, it shall be considered acceptable.
- Perindopril - For perindopril erbumine, any products labelled as 'Perindopril Tert-Butylamine' are acceptable. Erbumine and tert-butylamine are equivalent and used interchangeably.

7. Products with labels applied over any original packaging

The following products are those which are used in an aseptic setting and will receive a 'Critical' QA score if the product offered is supplied as re-boxed with an overlabelled primary container, or entirely over-labelled with a label in English that obscures or partly obscures the original text in another language.

NPC	Description
DPD881	NATALIZUMAB (TYRUKO) SOLUTION FOR INJECTION VIAL 300MG/15ML
DHB158	NATALIZUMAB (TYSABRI) SOLUTION FOR INJECTION VIAL 300MG/15ML