Prior Approval Scheme

NHS Devon Integrated Care Board

Version 2.0 February 2026

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2 Introduction

2.1 Health benefits must be maximised from the resources available. As new services become available, demand increases and procedures that give maximum health gain must be prioritised. This means that certain procedures will not be commissioned by Integrated Care Boards (ICBs) unless exceptional clinical grounds can be demonstrated.

2.2 To aid the maximisation of resources the NHS standard contract specifies that Co-ordinating Commissioners may operate a Prior Approval Scheme (PA Scheme) in accordance with Service Condition 29.17 to Service Condition 29.23 of the full NHS Standard Contract, and in accordance with Service Condition 29.8 to Service Condition 29.11 in the short-form NHS Standard Contract. In accordance with Service Condition 29.20 (Short-form SC29.8) the Co-ordinating Commissioner may at any time during a Contract Year give the Provider not less than one month's notice in writing of any new or replacement Prior Approval Scheme, or of any amendment to an existing Prior Approval Scheme. That new, replacement or amended Prior Approval Scheme must be implemented by the Provider on the date set out in the notice and will only be applicable to decisions to offer treatment made after that date.

2.3 The Prior Approval Scheme for NHS Devon ICB focuses on Evidence Based Interventions that are notified as national guidance and locally identified procedures of limited/low clinical effectiveness, aesthetic procedures, group prior approval for infrequent high cost and/or complex procedures and excluded drugs.

2.4 Application of this Prior Approval Scheme will ensure that the care the ICB commissions is based on sound evidence of clinical effectiveness. This will come from sources such as the National Institute for Health and Clinical Effectiveness (NICE), well designed systematic reviews and meta-analyses or randomised controlled trials.

2.5 Application of this Prior Approval Scheme means the ICB will commission health care services based solely on clinical need, within the resources available to the system. The ICB will not discriminate between individuals or groups on the basis of age, sex, sexuality, race, religion, lifestyle, occupation, social position, financial status, family status (including responsibility for dependants), intellectual/cognitive functioning or physical functioning.

2.6 All providers receiving referrals from NHS Devon ICB referring clinicians for clinical interventions either within contract, or as non-contract activity, the

provider shall be bound to deliver services in accordance with this Prior Approval scheme.

2.7 Commissioners shall not be required to pay a Provider in instances where the Prior Approval Scheme has not been complied with.

3. Evidence Based Interventions and NHS Devon ICB Clinical Interventions Local Policies

3.1 The Provider shall only provide activity in accordance with the NHS Devon ICB clinical commissioning policies, incorporating the requirements of Evidence Based Interventions that are included to the NHS Devon ICB Clinical Commissioning Policies. A link to the local policies https://onedevon.org.uk/our-work/services-and-support/medicines-and-treatments/nhs-devon-clinical-commissioning-policies/ and National Evidence Based Interventions is provided for information: Home - Evidence Based Interventions EBI. NHS Devon ICB require Providers to adhere to the local policies and clinical referral guidance as set out in the relevant formulary, and where these do not apply to the service in question then Providers are requested to follow the EBI guidance.

3.2 Where a provider does not comply with the NHS Devon ICB clinical commissioning policies fully, the commissioner shall not be required to pay for treatments that are outside of the scope of the policy in any circumstance other than where there is a specific agreement held in writing at the Provider that has been supplied by the ICB to fund as an Individual Funding Request.

4. Infrequent high cost and/or complex procedures or devices

4.1 Infrequent high cost and/or complex procedures/devices applies to all procedures/treatments not explicitly covered by contractual agreements.

4.2 However, should a clinician recommend their use, the provider must use the Individual Funding Request application route. The IFR policy and forms are available at Schedule 2G in the Particulars of your NHS Standard Contract with the ICB. Where a provider does not comply with IFR policy and does not hold a written notice of approval to proceed to treatment as an IFR by the NHS Devon the commissioner shall not be required to pay for treatments provided. Where a provider is providing services as a non-contracted provider, the Provide shall contact the ICB in accordance with the contract details at Appendix 1 to gain a copy of the IFR policy and forms.

5. Excluded Drugs and Devices

5.1 The provider shall apply the NHS Devon ICB Formulary, as included within your NHS Standard Contract Particulars included at Schedule 2G.

5.2 Nationally designated High cost drugs are listed within annex A at the following link: https://www.england.nhs.uk/publication/2025-26-nhs-payment-scheme/
High cost drugs commissioned by NHS England are available at the following link: NHS England » NHS England high cost drugs commissioning list
Drugs on this list for these indications, must not be charged to the ICB.

5.3 Providers need to ensure that appropriate hospital pharmacy or homecare arrangements are in place to pick up the prescribing/supply.

5.4 Where the ICB are the responsible commissioner, high-cost drugs are funded in line with NICE Technology Appraisals (TAs) unless the ICB has approved a local commissioning policy. The ICB reserves the right to undertake audits to ensure compliance with NICE.

5.5 The Provider will ensure that all PbR excluded medicines are charged to the appropriate commissioner e.g. NHS England (Specialised services), responsible ICB (locally commissioned services).

5.6 The ICB will only fund PbR excluded drugs at the PAS price/Commercial Medicines Unit tender price/ local tariff price where applicable. The Provider is required to submit evidence of procurement costs for all PbR excluded drugs on a monthly basis.

5.7 For the ICB to verify charges, monthly invoice data is to be submitted to the ICB. This data will contain a minimum of:

- Patient details (local patient identifier, GP M code)
- Drug details (drug; strength; quantity/pack size, formulation, date issued)
- Clinical directorate prescribing

5.8 Where a biological drug is required and there is a biosimilar available, we require all providers to use the lowest acquisition cost biological available. The best value biologic should be used in new and existing patients in line with the national commissioning framework. (https://www.england.nhs.uk/long-read/commissioning-framework-for-best-value-biological-medicines/). This in many cases will be the biosimilar.

5.9 The ICB requires providers to adhere in full to agreed Shared Care Policies, agreed Patient Group Directives (PGDs) and all NHS Devon medicines related local agreement. Relevant protocol or policies shall be included within your NHS Standard Contract Particulars included at Schedule 2G.

5.10 Providers shall not defer to GPs to prescribe on their behalf, except in accordance with any shared care arrangements identified within any individual NHS Devon ICB Policy/NHS Devon formulary.

6. Prior Approval Scheme process requirements

6.1 Only where there is a Prior Approval authorisation to treat and sufficient evidence to ensure that the individual Clinical Policy or Drug, procedure or device requirements set forth in this Prior Approval Scheme have been met, shall the Commissioner authorise the continuation by the Provider to deliver the activity following which the Commissioner shall make the associated payment in accordance with the NHS Standard Contract held between the Provider and the Commissioner.

6.2 All instances related to Mental Health ADHD or ASC Assessment and treatment where a Provider wishes to provide an activity that is referred to in this Prior Approval Scheme, the Provider MUST adhere to this Prior Approval Scheme described at Appendix 1. Similarly any treatment relating to weight management is described in Appendix 2

7. Payment and reconciliation related to any activity covered by this Prior Approval Scheme

7.1 Under no circumstances other than those identified within the Prior Approval Scheme shall the Commissioner be liable to fund any activity, drug, treatment or otherwise that is notified under this Prior Approval Scheme. The Commissioner reserves the right to contest payment that is not in accordance with this Prior Approval Scheme and the Provider agrees to refund the appropriate paid value. In accordance with Service Condition 29.18 (short-form SC29.9) the Provider must manage the Services and Referrals into them in accordance with the terms of any Prior Approval Scheme. If the Provider does not comply with the terms of any Prior Approval Scheme in providing a Service to a Service User, the Commissioners shall not be liable to pay for the Service provided to that Service User. The ICB shall monitor implementation of the PA Scheme as part of the reconciliation process, and as required issue notices of contested payment in accordance with Service Condition 36 (SC36).

Appendix 1: Prior Approval Process for Neurodiversity service providers

1.1 The provider shall work within NHS Devon Policies and service specification requirements for referral and assessment for Attention Deficit Hyperactivity Disorder (ADHD) and Autism Spectrum Condition (ASC).

1.2 It is required that providers are able to deliver a full pathway service, delivering assessment, diagnosis and treatment where clinically appropriate, which includes assessment with opportunity for the patient to receive virtual and potentially face to face consultations that take place within the area of the NHS Devon, it requires a notified assessment outcome to the referring practitioner. Where there is a confirmed diagnosis of ADHD, the titration and stabilisation of medication and ongoing prescribing of medicines (where shared care arrangements are not in place) are required by the provider. Alongside the ability to educate the patient on their diagnosis and signpost or refer to available support services provide follow up reviews and supporting shared care where this arrangement is agreed with the patient's GP.

1.3 Entering a shared care arrangement with any provider is at the discretion of the service users GP and Shared Care is with agreement of all parties i.e. specialist, GP and service user/family/carer.

1.4 Any service user who does not attend their agreed appointment (new or follow-up) may be discharged back to the care of their GP. The provider must ensure appropriate DNA policies are in place which include risk assessments, and no payment shall be due from the ICB.

Appendix 2: Prior Approval Process for Weight Management Services

1.1 Treatment must only be initiated in patients who meet the locally agreed eligibility criteria at the time of request. NB: locally agreed criteria may align with the national roll out programme defined by NHS England for the implementation of the NICE TA criteria, particularly for Tirzepatide and are subject to regular review by the NHS Devon ICB.

All Providers, including Primary care and community providers, must follow the NHS Devon weight management pathway ad criteria which are available on the ICB formulary website: https://devonformularyguidance.nhs.uk/)

1.3 All tier 3 and tier 4 weight management services are required to follow the locally commissioned eligibility and clinical criteria. All treatment requires prior approval before initiation where this is thought might fall outside local commissioned pathways.

1.4 Weight management drugs (e.g. GLP-1 receptor agonists including Semaglutide and Tirzepatide) are not listed on the national HCD list (see 5.2), therefore these drug costs are not eligible to be passed through to the commissioner, unless agreed by the ICB as part of a negotiated price and payment mechansim.

1.5 Providers cannot defer to GPs to prescribe GLP1 analogues for weight management on their behalf. The commissioned provider (secondary care or Tier 3/4) is responsible for all prescribing, monitoring and supply during treatment.

1.6 Providers are responsible for delivering (possibly involving sub-contracting) all elements of wraparound care and cannot rely upon elements being delivered by primary care services.

1.6 For patients already initiated on treatment outside this process, the provider must review for alignment with current criteria and, where necessary, reassess eligibility, discharge or refer appropriately.

1.9 The ICB reserves the right to carry out, or require the provider to carry out, audit to ensure compliance with commissioned criteria and the NHS Devon weight management pathway. This would be in accordance with GC15