12th December 2019

Contracting Lead - all providers

Dear Provider

Interventional Procedures Guidance – DDCCG Policy

After discussion with providers regarding implementation of the Derby and Derbyshire CCG’s (DDCCG) policy on IPG’s we write to clarify our position regarding Standard/ Normal arrangement IPGs.

The Derby and Derbyshire CCG policy on NICE Interventional Procedures Guidance (IPG), Medical Technologies Guidance (MTG), Diagnostics Guidance (DG) and Med Tech Innovation Briefing (MIB) is available at:

The IPG programme largely focused on how the treatment should be delivered within the NHS and there are four categories:

1. Normal arrangements: NICE has concluded that the evidence for the efficacy and safety of the procedure is deemed adequate and has recommended that clinicians should observe normal arrangements for governance, consent and audit.
2. Special arrangements: NICE has concluded that the procedure needs further evaluation and/or is an emerging technology. Clinicians wishing to use such a procedure are advised to inform their clinical governance lead, make special arrangements for consent and make special arrangements to audit and review their results.
3. Procedures which are recommended only to be carried out in the context of formal research studies approved by a research ethics committee. These are procedures which are still considered experimental.
4. Procedures which should not be used in the NHS. NICE has concluded that the evidence suggests that the procedure has no efficacy and/or poses unacceptable safety risks.

Clarification for Standard/Normal Arrangements;

- DDCCG will not challenge any standard/normal IPG’s that are already being carried out at our providers as of the date of this letter.
- As part of this agreement DDCCG requires a description/brief summary of the trusts internal governance process for approving procedures to be carried out, for assurance. Please send this to our Clinical Policies team via plc.v.priorapproval@nhs.net
- From the date of this letter, any new standard IPG’s/normal arrangements will require a business case to be submitted to DDCCG Clinical Policies Advisories Group for agreement.
For the remaining NICE IPG categories; ‘Special arrangements’, ‘Procedures which are recommended only to be carried out in the context of formal research studies approved by a research ethics committee’ and ‘Procedures which should not be used in the NHS’, DDCCG does not commission these and will not fund them under any circumstances. If a provider does carry out activity at its own risk, DDCCG requires a description of the trusts internal governance process for approving procedures for assurance.

NICE suggest the following governance arrangements:

<table>
<thead>
<tr>
<th>NICE IPG category</th>
<th>Suggested Governance Arrangement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Special arrangements</td>
<td>This recommendation means there are uncertainties about the procedure is safe and effective. We also recommend special arrangements if there are known risks of serious harm that need to be carefully explained to the patient before they make a decision. It emphasises the need for informed consent, both from the patient (or carer) and from senior medical staff, such as the clinical governance lead in their trust. Clinicians using the procedure should also collect data, for example by audit or research.</td>
</tr>
<tr>
<td>Research only</td>
<td>This means that the procedure should only be carried out in the context of formal research studies, as approved by a research ethics committee. We make this recommendation if the procedure is still considered to be experimental or because there are uncertainties that need to be resolved.</td>
</tr>
<tr>
<td>Do not use</td>
<td>We make this recommendation if the evidence suggests that the procedure doesn’t work well, or if there are unacceptable safety risks</td>
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</tbody>
</table>

Additional information can be found at: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/interventional-procedures-guidance/recommendations

Yours sincerely

Adam Reynolds
Head of Contract Management

cc. Trust Medical Director
Contract Manager