

BSSE APC Position Statement on Use of Manufacturers' Free of Charge Medicines Schemes where NICE Guidance is pending

Manufacturers' Schemes

A number of schemes designed to supply medicines that are undergoing NICE STA review free-of-charge prior to publication of the STA have been launched by the respective pharmaceutical manufacturers. The schemes state that the medicine will be supplied free of charge to patients who are anticipated will fit the future NICE STA criteria, prior to the STA publication, should the drug be approved by NICE in due course. The schemes state that if NICE do not approve the STA then the manufacturer will continue to supply free of charge until the patient and clinician decide that the medicines should be stopped. If NICE approve the STA, then the free supply ceases and the commissioner is expected to fund from either the date of publication or (in some cases) 3 months after STA publication, in line with the timescale that commissioners are expected to adhere to.

Considerations

- Manufacturer free of charge schemes mean that the NHS can receive free of charge supplies for individual patients for the loading dose period (if applicable) and for up to 90 days after the product receives NICE positive guidance.
- This is for cost of the medicine alone, and does not include the tariff activity charges that would be incurred by the CCG.
- The commissioners are concerned that the availability of such schemes may result in a devaluing of the NICE process, as a result of availability of these high cost medicines prior to NICE publication.
- In addition to devaluing the NICE process, this also reduces the impact of the BSSE APC process.
- If a negative NICE decision is published, the commissioners may still be expected to pick up the tariff activity costs, for activity that has not been commissioned.
- There is a concern that if the NICE STA does not publish the STA in line with the criteria anticipated by the scheme, then patients may be on treatment when they do not fit NICE criteria, and that agreement on medicines supply in this scenario is not covered by the scheme.
- There is concern that NICE STAs often state that patients who do not fit the criteria but have already started treatment can remain on the medicine. Should a NICE STA state this, then there is concern that free of charge schemes may be used to initiate patients on medication in a way ultimately not approved by NICE. This is a method of bypassing NICE guidance and is outside of the spirit the process.

Recommendation

The BSSE APC urges caution to CCGs or Trusts that are considering signing up to these schemes, and requests that Trusts notify the APC for awareness of any such schemes they sign up to.

Any patients initiated on medicines using one of these schemes by provider trusts and does not subsequently fit NICE criteria will continue to be funded by the initiating trust, at their own financial risk.

References

1. <http://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisals/Guide-to-the-single-technology-appraisal-process.pdf> <accessed 16.08.2016>
2. Policy for Pan-Mersey Area Prescribing Committee (APC) v1.5

Background

NICE

The NICE Single Technology Appraisal (STA) process is designed to provide recommendations, in the form of NICE guidance, on the use of new and existing medicines, products and treatments in the NHS.

The STA process is specifically designed to appraise a single product, device or other technology, with a single indication. The process normally covers new technologies (typically, new pharmaceutical products or licensed indications) and enables NICE to produce guidance soon after the technology is introduced in the UK.

An STA is based on a review of clinical and economic evidence principally provided by the manufacturer or sponsor. Clinical evidence measures how well the medicine or treatment works – the health benefits. The evidence includes the impact on quality of life (for example, pain relief, side effects and disability), and the likely effects on mortality. NICE also considers estimates of the associated costs, concentrating on costs to the NHS and personal social services (for example social services). The economic evidence shows how well the medicine or treatment works in relation to how much it costs the NHS and whether it represents value for money.