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| **Drug Name (Brand Name®, *Manufacturer*): Indication** |

1. Summary

Summarise, based on the considerations in the evaluation, whether the drug should be adopted for use. Consider whether, for example, particular stopping criteria or use under evaluation should be considered. Include place in therapy and alternative treatments where available.

Outline three key questions for the Committee to consider

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| Drug | RAG | Information |
| Efficacy vs. placebo |  |  |
| Efficacy vs. relevant comparator |  |  |
| Safety |  |  |
| Convenience |  |  |
| Budget impact for NCL |  |  |
| Recommendation in national or international guidance |  |  |

1. Background

Summarise briefly the disease, the drug in question, and alternative treatments. Consider whether the drug and indication are licensed / off-label / unlicensed. With particular reference to the drug for review, outline briefly NICE guidance in the therapeutic area or other best practice guidance in the absence of NICE (see [UKMi](http://www.ukmi.nhs.uk/activities/newProducts/default.asp?pageRef=3)).

1. Proposed place in therapy

Detail the proposed place in therapy as described by either the requesting clinician or the manufacturer; outline the nature of comparators.

1. Efficacy

Outline and summarise the clinical literature reviewed. Include a brief explanation of the trials included and the rationale for focusing on specific studies (for example, active comparator RCTs only may be considered, or a recent meta-analysis). For included studies summarise key characteristics; for RCTs, for example:

* The trial design including the population and any important inclusion/exclusion criteria
* The number of subjects and the allocation process
* The primary efficacy endpoint
* The key results and their statistical / clinical significance

Consider, for example, how internal and external validity of the trials might affect use in actual clinical practice; and what the absolute advantages of the drug are in comparison to a natural comparator – are there any direct comparisons, meta-analyses, Cochrane reviews etc, or can data from other registrational studies be used as a loose comparison.

How does this compare with current therapy? What are the limitations in comparing older studies with newer ones – study design, duration, patient populations, endpoints etc.

* 1. Relevant clinical trials which have not published

Search <https://clinicaltrials.gov/ct2/search/advanced> for studies which are planned however have not reported. Knowledge of forthcoming trials will support the Committee in understanding the degree of uncertainty surrounding the risk/benefit and may support the Committee in delaying a decision until the evidence base has matured.

Use the above link to identify the NCT number then enter the number into <https://scholar.google.co.uk/> to establish whether the study results are in the public domain.

1. Safety
   1. Key adverse events

Outline key safety data identified in the efficacy studies. Such safety considerations relate to the drug entity itself rather than its use in practice; as such the main focus will be to describe potential adverse drug reactions and any limitations in understanding their nature.

* 1. Risk assessment

Include any risks associated with administration.

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| Drug name | Prepared injectable  medicine | Therapeutic  risk | Use of concentrate | Complex calculation | Complex preparation | Reconstitute  vial | Part/multiple container | Use of infusion  pump/driver | Non standard infusion set | Total Risk Factors |
|  |  |  |  |  |  |  |  |  |  |  |

1. Cost-effectiveness

Give an outline of any data identified or a statement that health economic analyses are not available as necessary: No health economic data were identified.

Where an analysis exists, report:

* Key assumptions of the economic modelling
* Cost per QALY (or cost per gain in natural marker if no cost-utility analysis identified)
* Range of costs per QALY if sensitivity analysis reported

1. Convenience

Consider whether patient and/or healthcare provider convenience is affected by the drug. Consider: tolerability of the drug; acceptability of the drug and administration route by the patient; adherence to treatment (if assessed in trials, or if administration route could affect this); patient preference for this drug (if assessed in trials). Consider any practical information about drug administration, such as oral, SC injection.

1. Financial implications
   1. Likely commissioning and funding pathway

Consider the funding pathway—for example, whether the drug is in tariff or excluded; and whether commissioning will be through CCGs or NHS-E.

* 1. Drug cost

Choose an item.

Pack prices and annual/course cost per patient. Consider the drug’s cost in comparison with alternatives. Consider whether patient access schemes, for example, have an effect on comparative costs. Think about patents for alternatives.

* 1. Healthcare resource utilisation

Consider the potential effects on hospital attendances, for example, or other resource utilisation issues. Include details of monitoring required and frequency, and other tests required, e.g. endoscopies.

* 1. Budget impact

Consider the likely budgetary impact. If available this section might also report the estimated cost per 100 000 population; to include:

* The cost of treatment for an individual patient per unit of time
* Anticipated number of patients to be treated across Trust/NCL
* Estimated non-recurrent costs of adopting the technology per 100,000 population (and the epidemiological data that is based on)
* Estimated recurrent costs of adopting the technology per 100,000 population (and the epidemiological data that is based on)

1. Suitability for GP prescribing

Choose an item.

Shared care is not appropriate if patient numbers are low (<2/100 000 population).

Shared care should be reserved for drugs that require specialist involvement for patient selection, initiation, stabilisation and monitoring; and where regular monitoring is required on an ongoing basis and/or there is a need for specialist assessment for effectiveness/toxicity.

1. Legal status & procurement

Legal status: Choose an item.

Storage & handling requirements: Choose an item.

Consider access in the community for unlicensed medicines; is the drug available via Import or from a Special’s Manufacturer.

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| Author(s): |
| Job role: |
| Site: |
| Conflicts of interest: |
| JFC/DTC review date: |

References