

Checklist for Appraisal of Clinical Evidence.

Efficacy:

- Are the clinical trials valid?
- Are the results significant?
- Can the trial results be applied to the local population?
- Do the results apply to the patient that the drug is licensed in?
- can any comparisons be made with current standard therapy?
- Is sufficient evidence available to determine place alongside established treatments?

Innovation

- Is the product a first in class product?
- Does it offer any advantages over existing products available for the same indication?

Safety:

- Were there significant adverse effects seen in clinical trials?
- Is there a reduction in adverse effects compared to existing treatment options?
- Are there any monitoring requirements i.e. regular U&E tests etc
- Are there any specific patient subgroups warranting caution or contraindication e.g. CVD patients etc
- any relevant drug interactions with commonly used drugs.

Patient factors:

- Are there any advantages to patients or carers over existing treatments?
- What is the dose regimen? Would it encourage compliance/ concordance over existing treatments?
- If it's a device – ease of use, storage and cleaning need to be considered.

- Can it be stored in a dossette box?
- Use will lead to reduction in health inequality across the region?

Cost and affordability:

- will this have a substantial impact on primary care costs?
- will this have a substantial impact on secondary care costs?
- Is there a cost impact or cost saving outside the drug cost e.g. hospital admissions; length of stay, home visits for administration etc.
- Are there any special storage requirements or wastage of vials etc
- Are there any cost benefits outside of the NHS?
- Is there any specific cost effectiveness information available?

Clinical Pathway/Service implications:

- will this have a substantial impact on primary care workload?
- will this have a substantial impact on secondary care workload/service provisions?
- will this have an impact on the current treatment pathway?

Sustainability:

- does this have a lower carbon footprint?
- will this reduce environmental impact with the redesign of the services?
- source materials from and manufacture products within the UK (or relevant region)?
- reduces single use plastics, packaging and increases recyclability of products?

Deprescribing:

- will lead to changes in formulary and treatment pathway leading to deprescribing of some medicines/devices?
- patients will be regularly reviewed and consideration given to stopping this or other treatments?