**PACS 2 Decision Making Framework**

To be used when considering requests for medicines for individual patient use whether licensed or unlicensed.

**PACS 2 reference**

*(Where there are options Y/N please delete as appropriate, additional text space, using the grey text boxes are provided to include information which is not contained on the request form)*

**The panel should consider and note:**

1. **Clinical effectiveness**
2. Has the clinician demonstrated that a reasonable attempt, or appropriate consideration, has been made to treat the patient in the first instance with medicines currently accepted by the SMC for routine use in NHS Scotland for this condition and for the patient in question that these medicines are deemed unsuitable or have been found to be ineffective?

NO: (if negative the process should not continue)

YES:

1. Has the clinician presented an evidence-based case to demonstrate the potential that the patient will achieve a measurable clinical benefit at least comparable to if not better than that experienced by the population considered by the SMC

NO: (if negative the process should not continue)

YES:

1. Is the patient expected to achieve a clinical benefit better than experienced by the population or sub populations, considered by the SMC e.g. are there any individual patient characteristics for example genetic sub-types where the clinical evidence is stronger?

NO

UNCERTAIN

YES:

1. The strength of the available evidence (tick those that apply)

SMC DAD

Clinical Trials

Additional case studies etc.

Additional relevant information e.g. Medicine Information Summary

1. Nature of the benefit, when will occur and duration of benefit?

1. Likely response rate and/ or attributable risk reduction and how this differs from the population reviewed by SMC (if applicable)?

1. **Safety**
2. Are there any safety considerations in using this medicine in this individual case e.g. side effects/ health risks and likelihood of occurrence?

1. **Operational Impact**
2. Service Impact – for example chair time, clinic capacity etc.

1. Other considerations e.g. administration, regimen, travel etc.

1. Nursing impact – training/ expertise/ capacity

1. Pharmacy impact – is it in stock/ used before/ protocols in place? Impact on aseptic services/ capacity?

1. Other factors – space, equipment, diagnostics, etc.

1. Does this contribute to any NHS priorities e.g. care closer to home, waiting time reduction etc.

1. **Equity**
2. Has this medicine been approved for use in the same or similar circumstances within your NHS Board?

NO

YES:

1. Has this medicine been approved for use in the same or similar circumstances within UK?

NO

YES:

1. **Assessment of benefit to the NHS - health gain versus resource consumed**

Impact of the requested treatment on healthcare e.g. Cost effectiveness and affordability, and the balance of benefit and risk in the context of what is the wider benefit to the NHS**?**

Signed:

Date: