Principles to be used for decision making and pathway development for biologic use in situations not covered by NICE Technology Appraisal Guidance

MSEMOC recommended guidance

MSEMOC recommendation:

If NICE Technology Appraisal Guidance do not cover all potential uses of biologics* within a pathway and specialists would like to use them outside of the NICE TA recommendations then the following information must be submitted by the specialist for consideration:

1. what is the evidence for use for the indication and particular place in the pathway (including trials and national guidance)?
2. what is the rationale for use and predicted response rate?
3. does the proposed treatment have a different mode of action to alternative biologics?
4. what are the patient numbers at place in the pathway?
5. what are the outcomes if treatment effective/not effective?
6. what are the alternative treatment options (if any, including surgery)?
7. if treatment effective what is the treatment duration?
8. is there evidence for safe use in this cohort?
9. what are the costs if treatment effective/not effective?
10. is there any evidence of cost-effectiveness at place in the pathway?
11. if no alternatives what are the outcomes and costs of best supportive care?
12. have other CCGs agreed to fund this use?
13. if no evidence we expect order of use be based on use of least expensive appropriate biologic (in line with NICE's usual principles)
14. are there any new treatments in the pipeline that may affect pathway?

*For the purposes of decision making and pathway development the term 'biologic' will also apply to national tariff excluded high cost drugs that have been recommended by NICE TAs but are not biological medicines e.g. apremilast, dimethyl fumarate, janus kinase inhibitors etc.

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