Building a submission

AWTTC
All Wales Therapeutics
& Toxicology Centre

Questions

1. What studies could you include as relevant evidence in your submission to AWMSG? Are there any studies you would not include at all? If so, why not?
2. What treatments/comparators do you think are the most relevant to compare [treatment A] against? How would you compare the clinical effectiveness of [treatment A] to the comparators?
3. What clinical effectiveness evidence might be appropriate for the health economic model? Based on this, discuss what type of model (cost utility analysis or cost minimisation analysis) might be most appropriate.
4. Are there any factors that you might need to address in order to make your submission relevant to NHS Wales?

What studies could you include as relevant evidence in your submission to AWMSG? Are there any studies you would not include at all? If so, why not?

- The population used in the studies should reflect the scope/indication considered
- Treatment used should reflect licensed dose
- Focus on comparison of treatment of interest vs relevant comparators (provided this exists!)

What treatments/comparators do you think are the most relevant to compare osbournizab against?

- Licensed comparators are generally preferred
- Unlicensed off-label comparators may be appropriate if there are no other licensed options, and/or there is evidence of off-label use
- In this example, licensed comparator as base case + scenario analysis vs off-label comparator would be consistent with this whilst fully exploring clinical/cost implications

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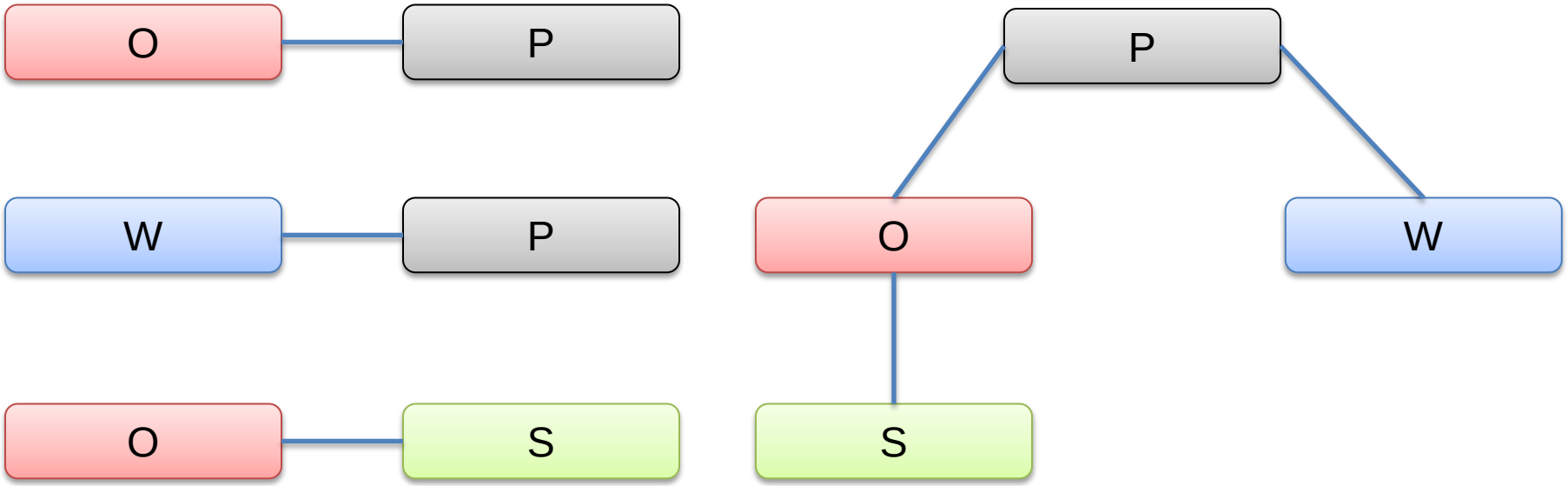
How would you compare the clinical effectiveness of osbournizab to the comparators?



What type of model (cost utility analysis or cost minimisation analysis) might be most appropriate?

- Cost utility analysis is always preferred
- CMA may be acceptable where there are no clinically meaningful differences between the medicine and its comparator(s).
- This should cover all dimensions of health, including impact on health outcomes, HRQoL, adverse events, patient preference and adherence.
- In this example: base case CUA, CMA vs off-label treatment as scenario analysis could be acceptable *if all measured outcomes were equivalent*

Factors that you might need to address in order to make your submission relevant to NHS Wales

- Trials conducted in different countries (some in Wales): could differences in demographics, or differences in disease definition/prevalence/care pathway affect relevance to Wales...?

Factors that you might need to address in order to make your submission relevant to NHS Wales

- UK-wide information gathered on comparators – could this differ specifically in NHS Wales?

- As part of appraisal, AWTTC consult Welsh clinical experts on current treatment options
- NMG/AWMSG use their own clinical judgement and the information provided by clinical experts to judge whether the comparators used in a submission are appropriate

Diolch

Thank you

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PAMS
Patient Access to Medicines Service

WNPU
Welsh National Poisons Unit

WeMeReC
Welsh Medicines Resource Centre

Yellowcard
Centre Wales

WAPSU
Welsh Analytical Prescribing Support Unit