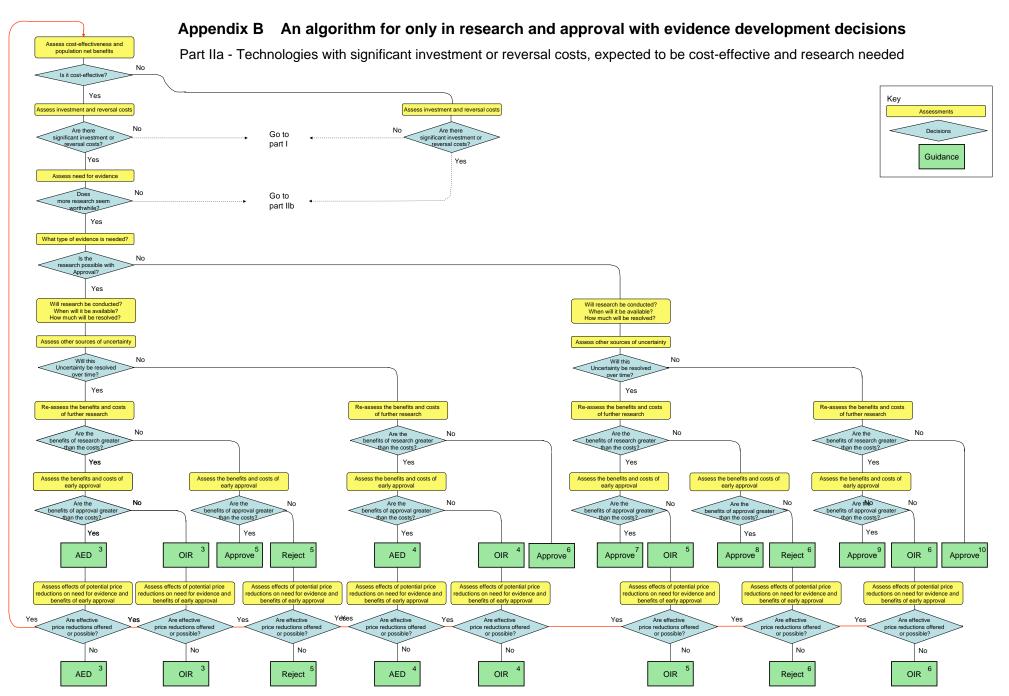


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## Appendix C An algorithm for only in research and approval with evidence development decisions Assess cost-effectiveness and Part IIb - Technologies with significant investment or reversal costs, not expected to be cost-effective or research not needed population net benefits Is it cost-effective? Yes Key Assessments Assess investment and reversal costs Assess investment and reversal costs Decisions Are there significant investment or Are there significant investment or Go to part I eversal costs? Guidance Yes Yes Assess need for evidence Assess need for evidence Does Does more research seem more research seem Yes Yes What type of evidence is needed? Is the esearch possible without Yes Go to part IIa Will research be conducted? Will research be conducted? When will it be available? When will it be available? How much will be resolved? How much will be resolved? Assess other sources of uncertainty Assess other sources of uncertainty Assess other sources of uncertainty Will this Will this Uncertainty be resolved Uncertainty be resolved Uncertainty be resolved over time? Yes Yes Re-assess the benefits and costs Re-assess the benefits and costs of further research of further research Are the No Are the benefits of research greater benefits of research greater than the costs? than the costs? Assess the benefits and costs of Assess the benefits and costs of Are the Are the benefits of approval greater benefits of approval greater than the costs? than the costs? Yes Yes Approve ' Reject Approve ' OIR Reject AED Reject Reject Assess effects of potential price eductions on need for evidence and eductions on need for evidence and eductions on need for evidence and reductions on need for evidence and reductions on need for evidence and benefits of early approval Are effective Are effective Are effective Are effective Are effective Are effective Yes price reductions offered or possible? or possible? or possible? or possible? or possible? No No No No No No Reject OIR Reject AED Reject Reject