# **Appendices**

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#### Appendix A An algorithm for only in research and approval with research decisions population net health effects Part II - Technologies with significant irrecoverable costs, expected to be cost-effective and research needed No Is it cost-effective? Yes Key Assessments Are there Are there Decisions Go to significant irrecoverable significant irrecoverable part I costs? costs? Guidance Yes Yes No Does Go to more research seem part III worthwhile? Yes What type of evidence is needed? Is the No research possible with Yes Assess other sources of uncertainty Assess other sources of uncertainty Uncertainty be resolved Uncertainty be resolved over time? overtime? Yes Yes Will research be conducted? When will it be available? How much will be resolved? Re-assess the benefits and costs No Are the benefits of research greater No Are the Are the Are the benefits of research greater benefits of research greater benefits of research greater than the costs? than the costs? than the costs? than the costs? Yes Assess the benefits and costs of early approval early approval Are the Are the Are the Are the Are the Are the benefits of approval greater Yes Yes Yes Yes Yes Yes OIR Reject OIR **AWR** OIR Approve Reject **AWR** Approve Approve OIR Approve Approve Approve Assess effects of potential price reductions on need for evidence and reductions on need for evidence and reductions on need for evidence and eductions on need for evidence and reductions on need for evidence and reductions on need for evidence and eductions on need for evidence and reductions on need for evidence and benefits of early approval Are effective price reductions offered price reductions offered price reductions offered or possible? No No No No No No No No AWR OIR AWR OIR OIR OIR Reject Reject

#### Appendix A An algorithm for only in research and approval with research decisions Assess cost-effectiveness and population net health effects Part III - Technologies with significant irrecoverable costs, not expected to be cost-effective or research not needed No Is it cost-effective? Key Yes Assessments Assess irrecoverable costs Assess irrecoverable costs Decisions Are there No Are there Go to significant irrecoverable significant irrecoverable part I costs? costs? Guidance Yes Yes Assess need for evidence Assess need for evidence No No Does Does more research seem more research seem worthwhile? worthwhile? Yes Yes What type of evidence is needed? Is the research possible without Approval? Yes Go to Assess other sources of uncertainty Assess other sources of uncertainty Assess other sources of uncertainty No Willthis No No Will this Will this Uncertainty be resolved Uncertainty be resolved Uncertainty be resolved Yes Yes Yes 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? Re-assess the benefits and costs Re-assess the benefits and costs of further research of further research Are the benefits of research greater Are the benefits of research greater than the costs? Yes Yes Assess the henefits and costs of Assess the benefits and costs of early approval early approval No No Are the Are the benefits of approval greater benefits of approval greater than the costs? than the costs? Yes Yes Reject<sup>11</sup> Reject Approve<sup>'</sup> OIR Reject AWR Reject Approve ' Assess effects of potential price Assess effects of potential price reductions on need for evidence and Assess effects of potential price reductions on need for evidence and benefits of early approval Are effective Are effective Are effective Are effective price reductions offered or possible? or possible? or possible? or possible? or possible? or possible? No No No No No Reject<sup>11</sup> OIR Reject AWR Reject Reject

# Appendix B

Table B1 Types and categories of guidance from using the checklist

Assessment	1	2	3	4	5	6	7	Guidance
1	Yes	No	Yes	Yes	Yes/No	Yes	-	AWR 1
2	Yes	No	Yes	Yes	Yes/No	No	-	Approve 1
3	Yes	No	Yes	No	Yes/No	Yes	Yes	Approve 2
4	Yes	No	Yes	No	Yes/No	Yes	No	OIR 1
5	Yes	No	Yes	No	Yes/No	No	-	Approve3
6	Yes	No	No	-	-	-	-	Approve 4
7	No	No	Yes	Yes	Yes/No	Yes	-	OIR 2
8	No	No	Yes	Yes	Yes/No	No	-	Reject 1
9	No	No	Yes	No	Yes/No	Yes	Yes	AWR 2
10	No	No	Yes	No	Yes/No	Yes	No	Reject 2
11	No	No	Yes	No	Yes/No	No	-	Reject 3
12	No	No	No	-	-	-	-	Reject 4
13	Yes	Yes	Yes	Yes	Yes	Yes	Yes	AWR 3
14	Yes	Yes	Yes	Yes	Yes	Yes	No	OIR 3
15	Yes	Yes	Yes	Yes	Yes	No	Yes	Approve 5
16	Yes	Yes	Yes	Yes	Yes	No	No	Reject 5
17	Yes	Yes	Yes	Yes	No	Yes	Yes	AWR 4
18	Yes	Yes	Yes	Yes	No	Yes	No	OIR 4
19	Yes	Yes	Yes	Yes	No	No	-	Approve 6
20	Yes	Yes	Yes	No	Yes	Yes	Yes	Approve 7
21	Yes	Yes	Yes	No	Yes	Yes	No	OIR 5
22	Yes	Yes	Yes	No	Yes	No	Yes	Approve 8
23	Yes	Yes	Yes	No	Yes	No	No	Reject 6
24	Yes	Yes	Yes	No	No	Yes	Yes	Approve 9
25	Yes	Yes	Yes	No	No	Yes	No	OIR 6
26	Yes	Yes	Yes	No	No	No	-	Approve 10
27	Yes	Yes	No	n/a	Yes	n/a	Yes	Approve 11
28	Yes	Yes	No	n/a	Yes	n/a	No	Reject 7
29	Yes	Yes	No	n/a	No	-	-	Approve 12
30	No	Yes	Yes	Yes	Yes/No	Yes	-	OIR 7
31	No	Yes	Yes	Yes	Yes/No	No	-	Reject 8
32	No	Yes	Yes	No	Yes/No	Yes	Yes	AWR 5
33	No	Yes	Yes	No	Yes/No	Yes	No	Reject 9
34	No	Yes	Yes	No	Yes/No	No	-	Reject 10
35	No	Yes	No	-	-	-	-	Reject 11
-		. 20						,

Part I of the algorithm

Part II of the algorithm

Part III of the algorithm

## Appendix C

Figure C1 Possible pathways for CLOP Assess cost-effectiveness and population net health effects Key Assessments No Is it cost-effective? Decisions Go to Yes Appendix A Part I Guidance Assess irrecoverable costs No Are there significant irrecoverable Yes Assess need for evidence No Go to Does more research seem worthwhile? Appendix A Part I Yes Go to What type of evidence is needed? Appendix A part II Is the No research possible with Approval? Yes Assess other sources of uncertainty No Will this Uncertainty be resolved over time? Go to Appendix A Will research be conducted? Part I When will it be available? How much will be resolved? Re-assess the benefits and costs of further research No Are the benefits of research greater than the costs? Assess the benefits and costs of early approval Are the benefits of approval greater No

than the costs?

Approve

OIR

Approve

Figure C2 Possible pathways for EECP

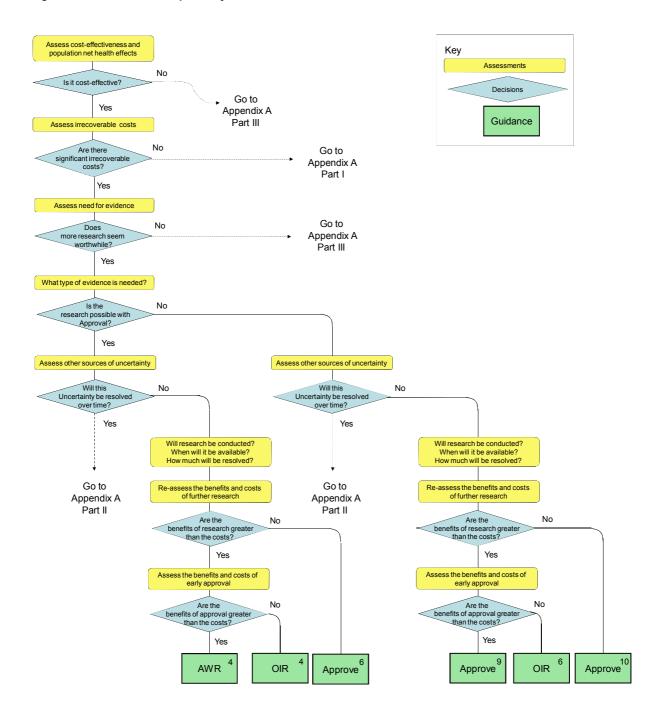


Figure C3 Possible pathways for OMAL

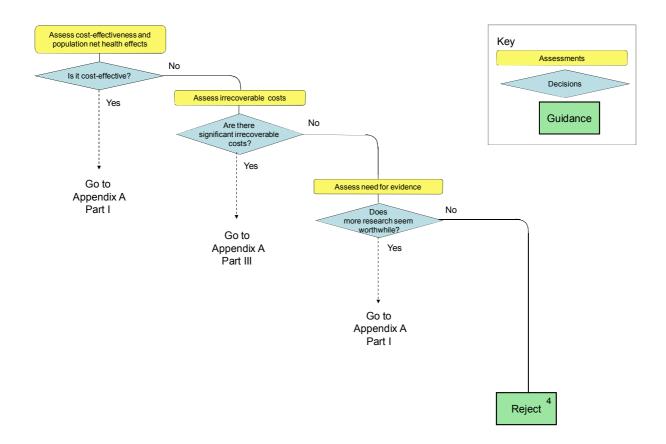


Figure C4 Possible pathways for PsA

