**NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE**

**CENTRE FOR HEALTH TECHNOLOGY EVALUATION**
**Technology Appraisals**

# Consultation on Batch 13 draft remits and draft scopes

Summary of comments and discussions at scoping workshops

| **Batch 13 topics** |
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| Cabazitaxel for the second line treatment of hormone refractory, metastatic prostate cancer |
| Retigabine for the adjunctive treatment of partial onset seizures in epilepsy |
| Eribulin for the treatment of locally advanced or metastatic breast cancer |
| Adalimumab for the treatment of acute exacerbations of ulcerative colitis |
| Adalimumab for the treatment of sub-acute exacerbations of ulcerative colitis |
| Pralatrexate for the treatment of relapsed or refractory peripheral T-cell lymphoma |

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| **Provisional Title** | Cabazitaxel for the second line treatment of hormone refractory, metastatic prostate cancer |
| **Topic Selection ID Number** | 4322 |
| **Wave** | 23 |
| **Anticipated licensing information** | Confidential |
| **Draft remit** | To appraise the clinical and cost effectiveness of cabazitaxel within its licensed indication for the second line treatment of hormone refractory, metastatic prostate cancer. |
| **Main points from consultation** | Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of cabazitaxel for the second-line treatment of hormone-refractory metastatic prostate cancer is appropriate.<br><br>The proposed remit is not appropriate. It should be amended to reflect the fact that the technology is only considered for use in people whose disease has relapsed or is refractory to docetaxel containing chemotherapy regimens. |
| **Process (MTA/STA)** | STA |
| **Proposed changes to remit (in bold)** | To appraise the clinical and cost effectiveness of cabazitaxel within its licensed indication for the treatment of hormone-refractory metastatic prostate cancer **previously treated with docetaxel chemotherapy regimens.** |
| **Costing implications of remit change** | No impact – initial cost impact was based on the technology only being considered for use following failure of docetaxel treatment. Cost of cabazitaxel was and remains unknown. |
| **Timeliness statement** | Assuming the anticipated date of the marketing authorisation is the latest date that we are aware of and the expected referral date of this topic, issuing timely guidance for this technology will be possible. |

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| **Provisional Title** | Retigabine for the adjunctive treatment of partial onset seizures in epilepsy |
| **Topic Selection ID Number** | 4324 |
| **Wave** | 23 |
| **Anticipated licensing information** | Confidential |
| **Draft remit** | To appraise the clinical and cost effectiveness of retigabine within its licensed indication for the adjunctive treatment of partial onset seizures in epilepsy with and without secondary generalisation. |
| **Main points from consultation** | Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of retigabine for the adjunctive therapy of partial onset seizures in epilepsy is appropriate.<br><br>The proposed remit is not appropriate. It was recommended at the scoping workshop that it should be amended to reflect the patient population enrolled in the relevant clinical trials and incorporated into the marketing authorisation. |
| **Process (MTA/STA)** | STA |
| **Proposed changes to remit (in bold)** | To appraise the clinical and cost effectiveness of retigabine within its licensed indication for the adjunctive treatment of **adults** with partial onset seizures in epilepsy with and without secondary generalisation. |
| **Costing implications of remit change** | Initial costing work was unable to estimate cost impact as the cost of the drug was unknown. The impact of the proposed change to remit would be to reduce the estimated population if it is not considered in children. |
| **Timeliness statement** | Assuming the anticipated date of the marketing authorisation is the latest date that we are aware of and the expected referral date of this topic, issuing timely guidance for this technology will be possible. |

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| **Provisional Title** | Eribulin for the treatment of locally advanced or metastatic breast cancer |
| **Topic Selection ID Number** | 4181 |
| **Wave** | 23 |
| **Anticipated licensing information** | Confidential |
| **Draft remit** | To appraise the clinical and cost effectiveness of eribulin within its licensed indication for the treatment of locally advanced or metastatic breast cancer. |
| **Main points from consultation** | Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of eribulin for the treatment of locally advanced or metastatic breast cancer is appropriate.<br><br>Consultees considered that the remit was appropriate. However, the Institute recommends that the remit should reflect the place in the care pathway where eribulin will be licensed. This is to ensure that this proposed appraisal of eribulin can be differentiated from any future appraisals of eribulin in the advanced or metastatic breast cancer setting. |
| **Process (MTA/STA)** | STA |
| **Proposed changes to remit (in bold)** | To appraise the clinical and cost effectiveness of eribulin **monotherapy** within its licensed indication for the **treatment of people with breast cancer who have received two or more chemotherapy regimens for locally advanced or metastatic disease.** |
| **Costing implications of remit change** | No impact – initial cost impact was based on the technology only being considered for use third line. Cost of eribulin was and remains unknown. |
| **Timeliness statement** | Assuming the anticipated date of the marketing authorisation is the latest date that we are aware of and the expected referral date of this topic, issuing timely guidance for this technology will be possible. |

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| **Provisional Title** | Adalimumab for the treatment of acute exacerbations of ulcerative colitis |
| **Topic Selection ID Number** | 4486 |
| **Wave** | 24 |
| **Anticipated licensing information** | Confidential |
| **Draft remit** | To appraise the clinical and cost effectiveness of adalimumab within its licensed indication for the treatment of acute exacerbations of severely active ulcerative colitis that require hospitalisation. |
| **Main points from consultation** | Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of adalimumab for the treatment of moderately to severely active ulcerative colitis is appropriate.<br><br>It was recommended that the draft remit was not appropriate and that the two proposed batch 13 appraisals of adalimumab for the treatment of acute exacerbations of ulcerative colitis and adalimumab for the treatment of sub-acute exacerbations of ulcerative colitis should be appraised as a single topic; adalimumab for the treatment of moderate to severe ulcerative colitis. There are no existing or planned studies of adalimumab in people with acute ulcerative colitis that requires hospitalisation. Although separate appraisals of infliximab for acute exacerbations (TA163) and sub-acute exacerbations (TA140) were completed, these were feasible only because data had been available for both acute ulcerative colitis that requires hospitalisation and sub-acute ulcerative colitis (defined as disease that would normally be managed in an outpatient setting and that does not require hospitalisation or the consideration of urgent surgical intervention). It was considered for this appraisal that it would be appropriate to identify people with acute exacerbations requiring hospitalisation as a subgroup to be examined if evidence allowed. |
| **Process (MTA/STA)** | STA |
| **Proposed changes to remit (in bold)** | To appraise the clinical and cost effectiveness of adalimumab within its licensed indication **for the treatment of moderate to severe ulcerative colitis**. |
| **Costing implications of remit change** | No impact on original cost estimate that this is potentially cost saving as the cost per patient is cheaper than infliximab in this indication. |
| **Timeliness statement** | Assuming the anticipated date of the marketing authorisation is the latest date that we are aware of and the expected referral date of this topic, issuing timely guidance for this technology will be possible. |

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| **Provisional Title** | Adalimumab for the treatment of sub-acute exacerbations of ulcerative colitis |
| **Topic Selection ID Number** | 4486 |
| **Wave** | 24 |
| **Anticipated licensing information** | Confidential |
| **Draft remit** | To appraise the clinical and cost effectiveness of adalimumab within its licensed indication for the treatment of sub-acute manifestations of moderate to severe ulcerative colitis. |
| **Main points from consultation** | Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of adalimumab for the treatment of moderately to severely active ulcerative colitis is appropriate.<br><br>It was recommended that the draft remit was not appropriate and that the two proposed batch 13 appraisals of adalimumab for the treatment of acute exacerbations of ulcerative colitis and adalimumab for the treatment of sub-acute exacerbations of ulcerative colitis should be appraised as a single topic; adalimumab for the treatment of moderate to severe ulcerative colitis. There are no existing or planned studies of adalimumab in people with acute ulcerative colitis that requires hospitalisation. Although separate appraisals of infliximab for acute exacerbations (TA163) and sub-acute exacerbations (TA140) were completed, these were feasible only because data had been available for both acute ulcerative colitis that requires hospitalisation and sub-acute ulcerative colitis (defined as disease that would normally be managed in an outpatient setting and that does not require hospitalisation or the consideration of urgent surgical intervention). It was considered for this appraisal that it would be appropriate to identify people with acute exacerbations requiring hospitalisation as a subgroup to be examined if evidence allowed. |
| **Process (MTA/STA)** | |
| **Proposed changes to remit (in bold)** | Not applicable. Please see prior recommendations for the previous topic adalimumab for the treatment of moderate to severe ulcerative colitis. |
| **Costing implications of remit change** | |
| **Timeliness statement** | |

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| **Provisional Title** | Pralatrexate for the treatment of relapsed or refractory peripheral T-cell lymphoma |
| **Topic Selection ID Number** | 4192 |
| **Wave** | 24 |
| **Anticipated licensing information** | Confidential |
| **Draft remit** | To appraise the clinical and cost effectiveness of pralatrexate within its licensed indication for the treatment of relapsed or refractory peripheral T-cell lymphoma. |
| **Main points from consultation** | Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of pralatrexate for the treatment of relapsed or refractory peripheral T-cell lymphoma is appropriate.<br><br>The draft remit is appropriate |
| **Process (MTA/STA)** | STA |
| **Proposed changes to remit (in bold)** | No changes proposed |
| **Costing implications of remit change** | No impact on original cost impact assessment |
| **Timeliness statement** | Assuming the anticipated date of the marketing authorisation is the latest date that we are aware of and the expected referral date of this topic, issuing timely guidance for this technology will be possible. |