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| 1 | <p>Treatment & Condition <i>(Title)</i></p> <p>NICE Technology Appraisal Guidance TA345 Naloxegol for treating opioid-induced constipation</p> |
| 2 | <p>Associated appraisal body & Summary of ruling <i>(to include indication, restrictions, other relevant information)</i></p> <p>NICE technology appraisal guidance 345 (July 2015)</p> <p>NICE TA345 recommends Naloxegol, within its marketing authorisation, as an option for treating opioid induced constipation in adults whose constipation has not adequately responded to laxatives. An inadequate response is defined as opioid-induced constipation symptoms of at least moderate severity in at least 1 of the 4 stool symptom domains (that is, incomplete bowel movement, hard stools, straining or false alarms) while taking at least 1 laxative class for at least 4 days during the prior 2 weeks.</p> <p>Naloxegol can be used as an alternative to methylnaltrexone and would be similarly positioned in the treatment pathway after treatment with a stimulant and osmotic laxative had failed.</p> |
| 3 | <p>Number of people in Northern Ireland expected to take up service/therapy <i>(including new cases per year)</i></p> <p>NICE advises that this new therapy is best considered as an alternative to methylnaltrexone and should be similarly positioned in the patient pathway. While the indications for both medicines are comparable, Methylnaltrexone should be administered subcutaneously and closely monitored, while Naloxegol is given orally and is hence easier to use.</p> <p>It may therefore lead to increased drug costs where it is used off label in place of conventional laxative treatments, but generate cost savings if it is used as an alternative to methylnaltrexone as recommended by NICE.</p> <p>In NI in last 12 months there were only 3 patients for methylnaltrexone in primary care at a total cost of £252; the cost for naloxegol would have been £165.60, so savings to primary care prescribing budget will be minimal.</p> <p>During the same period there were an estimated 1 or 2 hospital prescriptions for methylnaltrexone per month in NI. Therefore if used within its licence the introduction of naloxegol could lead to a small saving.</p> |

| | While its administration is easier the side effect profile of naloxegol is similar to that of methylalntrexone and it is therefore unlikely that naloxegol will be used much more commonly than its comparator despite its easier use. | | | | | | | | | | | | | | | |
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| 4 | Patient Access Scheme availability Not applicable | | | | | | | | | | | | | | | |
| 5 | Costs (<i>before PAS if applicable</i>) | | | | | | | | | | | | | | | |
| 5.1 | <p>Drug cost per patient per annum (for new and prevalent cases)</p> <p>The list price for naloxegol is £55.20 per 30-tablet pack of 12.5-mg or 25-mg film-coated tablets. The recommended dose is 25 mg once daily or 12.5 mg for people with renal insufficiency. The estimated drug cost of each treatment is shown in table 1.</p> <p>Table 1</p> <table border="1"> <thead> <tr> <th>Treatment</th> <th>Regimen</th> <th>Treatment Cost (£)</th> </tr> </thead> <tbody> <tr> <td>Naloxegol</td> <td>25 mg taken orally once daily (12.5 mg for people with renal insufficiency)</td> <td>671.60</td> </tr> <tr> <td>Methylalntrexone (4 months of treatment)</td> <td>Subcutaneous injection, every 2 days</td> <td>1284.05</td> </tr> <tr> <td>Naloxone-oxycodone c</td> <td>25 mg/10 mg taken orally every 12 hours</td> <td>1103.08</td> </tr> <tr> <td>Bisacodyl</td> <td>5 mg taken orally once daily</td> <td>12.52</td> </tr> </tbody> </table> | Treatment | Regimen | Treatment Cost (£) | Naloxegol | 25 mg taken orally once daily (12.5 mg for people with renal insufficiency) | 671.60 | Methylalntrexone (4 months of treatment) | Subcutaneous injection, every 2 days | 1284.05 | Naloxone-oxycodone c | 25 mg/10 mg taken orally every 12 hours | 1103.08 | Bisacodyl | 5 mg taken orally once daily | 12.52 |
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| 5.2 | Infrastructure costs per patient per annum None | | | | | | | | | | | | | | | |
| 5.3 | Current in year costs The implementation of the technology is not anticipated to have any significant cost implications as it is another option to existing treatments for this condition. | | | | | | | | | | | | | | | |
| 5.4 | Recurrent overall costs per annum (<i>including additional costs</i>) The implementation of the technology is not anticipated to have any significant cost implications as it is an option for an existing treatment. | | | | | | | | | | | | | | | |
| 5.5 | Opportunities for cost savings and how these will be secured Naloxegol is orally administered and could decrease demands on staffing time for providers when used in place of methylalntrexone, which is a subcutaneous injection. | | | | | | | | | | | | | | | |

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| | As uptake for this treatment will be not be significant, any cost savings will be minimal |
| 6 | Expected implementation period Immediate |
| 7 | Commissioning arrangements Not applicable |
| 8 | Monitoring arrangements Not applicable |
| 9 | DHSSPS Legislative/Policy Caveats This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case. |