

Equality and Health Impact Assessment

Panitumumab (Vectibix), for treatment of stage IV metastatic left-sided colorectal cancer with RAS wildtype confirmed by circulating tumour DNA following successful first line treatment with an epidermal growth factor inhibitor and at least one other treatment (OW29)

AWTTC will fill in an Equality and Health Impact Assessment in parallel with each development stage of our projects. This will help us to follow the five ways of working for public bodies, and work to achieving the wellbeing goals, outlined in the Well-Being of Future Generations (Wales) Act 2015.

Date: 06/03/2025

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| 1. | AWTTC contact details | Tel: 02921 826900 Email: awttc@wales.nhs.uk |
| 2. | State the objectives of the project. | <p>AWTTC will prepare an evidence status report (ESR) for an assessment through the One Wales Medicines process for the use of panitumumab (Vectibix) as a re-challenge, for the third-line or later treatment of metastatic colorectal cancer after previous successful use of an epidermal growth factor receptor inhibitor (EGFRi).</p> <p>The ESR will summarise rationale for the assessment, clinical effectiveness, safety considerations, cost effectiveness and budget impact. AWTTC will request the views of patient organisations relevant to the condition, and will send the ESR to the company (marketing authorisation holder) and to clinicians in Wales for comment. Clinicians, company representatives and patient organisation representatives will be invited to attend the meeting of the One Wales Medicines Assessment Group (OWMAG) to consider the ESR. The OWMAG constitution is available online.</p> |
| 3. | Evidence and background information considered. For example: | Metastatic colorectal cancer (mCRC) refers to malignant disease that has spread beyond the large intestine and nearby lymph nodes. Patients with |



- population data
- staff and service users' data, as applicable
- needs assessment
- engagement and involvement findings
- research
- good practice guidelines
- participant knowledge
- list of stakeholders and how stakeholders have engaged in the development stages
- comments from those involved in the designing and development stages

[Population pyramids](#) are available from Public Health Wales Observatory.

Stage IV mCRC have a poor prognosis, with 1-year survival rates of approximately 44%, and 5-year survival rates of less than 10%.

Clinicians in Wales submitted panitumumab as a third-line and above treatment option for mCRC for consideration through the One Wales process. They consider there is an unmet need in Wales and have identified a cohort of patients who could benefit from this treatment.

Patients who have RAS wild-type (non-mutated) tumour DNA may be treated with an EGFRi such as panitumumab in combination with chemotherapy. Over time, RAS mutations can develop leading to resistance to EGFRi treatment and cancer progression, and treatment with the EGFRi is withdrawn. In the absence of an EGFRi, RAS mutations may dwindle and wild-type status return, giving an opportunity to re-challenge with an EGFRi.

The genomic status of tumours can be assessed using liquid biopsy. A liquid biopsy analyses circulating tumour DNA (ctDNA) from cancerous cells and tumours in the bloodstream. The analysis can detect and diagnose tumour mutations and help to determine treatment choice. Clinicians propose to use liquid biopsy to find out if RAS mutations have dwindled, leading to a reduction in resistance to EGFRi and indicating an opportunity to re-challenge with panitumumab.

The current UK clinical pathway for this cohort of patients is first-line EGFRi (either panitumumab or cetuximab) in combination with chemotherapy. On development of resistance the EGFRi is stopped and chemotherapy alone (second-line) continues. Third-line therapy would be trifuridine/tipiracil (Lonsurf) in combination with bevacizumab; regorafenib monotherapy or Lonsurf. Panitumumab re-challenge is proposed as an option for third-line and above therapy. The dose of panitumumab is 6 mg/kg administered by intravenous infusion every two weeks (the same as the licensed dose). This use of panitumumab is off-label; panitumumab is not licensed for use at this stage in the treatment pathway.



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| | | Clinicians in Wales estimate between 30 and 60 people in Wales might be eligible for treatment with panitumumab re-challenge. The duration of treatment is uncertain; in one clinical study the median duration of response was 17 weeks. |
| 4. | Who will this project affect? | People in Wales with metastatic colorectal cancer, if the criteria for treatment are met, and their families and carers. |

5. EQIA - How will the project impact on people?

Questions in this section relate to the impact on people based on their 'protected characteristics'.

| How will the project impact on, or affect: | Potential positive and/or negative impacts | Recommendations for improvement/ mitigation | Actions taken (and who by). |
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| <p>5.1 Age For most purposes, the main categories are people aged:</p> <ul style="list-style-type: none"> • under 18 years; • between 18 and 65 years; • over 65 years. | <p>We do not expect a potential negative, or unequal, impact on people based on their age.</p> <p>[Note: Panitumumab is not licenced for this indication, the risks and benefits of the off-label use of panitumumab should be clearly stated and discussed with the patient to allow informed consent. Providers should consult the General Medical council Guidelines on prescribing unlicensed medicines before any off-label medicines are prescribed. Healthcare professionals should take note of the contraindications, warnings, safety recommendations and any monitoring needs for the</p> | <p>N/A</p> | <p>N/A</p> |



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| | medicine. These are explained in the Summary of Product Characteristics (SmPC) for the medicine or the British National Formulary . | | |
| 5.2 Persons with a disability as defined in the Equality Act 2010 Those with physical impairments, learning disability, sensory loss or impairment, mental health conditions, long-term medical conditions such as diabetes. | We do not expect a potential negative, or unequal, impact on people with a disability. | All related documents published on the AWTTC website will meet accessibility requirements. Any patient-facing materials will be also be produced as easy read booklets in Welsh and English. | N/A |
| 5.3 People of different genders: Consider men, women, people undergoing gender reassignment. N.B. Gender-reassignment is anyone who proposes to, starts, is going through or who has completed a process to change his or her gender with or without going through any medical | We do not expect a potential negative, or unequal, impact on people based on their gender, or on people undergoing gender reassignment. | N/A | N/A |



| How will the project impact on, or affect: | Potential positive and/or negative impacts | Recommendations for improvement/ mitigation | Actions taken (and who by). |
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| procedures. Sometimes referred to as Trans or Transgender. | | | |
| 5.4 People who are married or who have a civil partner. | We do not expect a potential negative, or unequal, impact on people based on their marital status or being in a civil partnership. | N/A | N/A |
| 5.5 Women who are expecting a baby, who are on a break from work after having a baby, or who are breastfeeding. They are protected for 26 weeks after having a baby whether or not they are on maternity leave. | Panitumumab has the potential to cause foetal harm when administered during pregnancy. Women of childbearing potential must use appropriate contraceptive measures during therapy and for 2 months after discontinuation of panitumumab (refer to the SmPC). Panitumumab might be secreted into breast milk with the potential for absorption and harm to the infant unknown. The manufacturer recommends that women do not breastfeed | Prescribers should take account of the SmPC when prescribing any medicines for women who are pregnant, or who are breastfeeding. | The SmPC criteria specify which people are excluded from treatment due to the associated risks of treatment. This will be identified for consideration of any change to the advice at the next review if there is a change to the current advice for pregnant and breastfeeding women. |



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| | during treatment with panitumumab and for 2 months after the last dose (refer to the SmPC). | | |
| <p>5.6 People of a different race, nationality, colour, culture or ethnic origin including non-English speakers, gypsies and travellers, migrant workers.</p> <p>The Runnymede Trust</p> | We do not expect a potential negative, or unequal, impact on people of a different race, nationality, colour, culture or ethnic origin. | N/A | N/A |
| <p>5.7 People with a religion or belief or with no religion or belief.</p> <p>The term ‘religion’ includes a religious or philosophical belief.</p> <p>Implications of religious beliefs on selection of medicines (BMJ)</p> <p>In practice: guidance on religion, personal values and beliefs (General Pharmaceutical Council)</p> | We do not expect a potential negative, or unequal, impact on people who have a religion or belief, or people with no religion of belief. | N/A | N/A |
| <p>5.8 People who are attracted to other people of:</p> <ul style="list-style-type: none"> the opposite sex (heterosexual); | We do not expect a potential negative, or unequal, impact on people based on who they are attracted to. | N/A | N/A |



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| <ul style="list-style-type: none">the same sex (lesbian or gay);both sexes (bisexual). Stonewall | | | |
| 5.9 People who communicate using the Welsh language in terms of correspondence, information leaflets, or service plans and design. | <p>We do not expect a potential negative, or unequal, impact on people who communicate using the Welsh language.</p> <p>Any patient-facing materials will be produced in Welsh and English, in line with the Welsh language standards, including easy read booklets.</p> | <p>Any patient-facing materials will be produced in Welsh and English, in line with the Welsh language standards, including easy read booklets.</p> | N/A |
| 5.10 People according to their income related group. | <p>We do not expect a potential negative, or unequal, impact on people based on their income-related group.</p> <p>In Wales, all prescription medicines are free-of-charge for patients; positive recommendations through this project will not affect people depending on their income-related group.</p> | N/A | N/A |



| How will the project impact on, or affect: | Potential positive and/or negative impacts | Recommendations for improvement/ mitigation | Actions taken (and who by). |
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| | This is a treatment administered by IV infusion, which will require attendance at hospital every 2 weeks. This may be an additional cost burden for patients who live a distance from the nearest treatment centre. | | |
| 5.11 People according to where they live. | This is a treatment administered by IV infusion, which will require attendance at hospital every 2 weeks. This may have an unequal impact on patients who live a distance from the nearest treatment centre who may find the additional travel burdensome, especially as patients with metastatic colorectal cancer may be in pain and discomfort. | N/A | N/A |
| 5.12 Consider others who face health inequalities, such as: | We do not expect a potential negative, or unequal, impact on others who face health | N/A | N/A |



| How will the project impact on, or affect: | Potential positive and/or negative impacts | Recommendations for improvement/ mitigation | Actions taken (and who by). |
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| <ul style="list-style-type: none">• Looked after and accommodated children and young people• Carers: paid/unpaid, family members• People who are homeless or those who experience homelessness: people on the street; those staying temporarily with friends/family; those in hostels/B&Bs• People involved in the criminal justice system: offenders in prison or on probation, ex-offenders• People with addictions and substance misuse problems• People who have poor literacy• People living in remote, rural and island locations | inequalities. Carers for someone with metastatic colorectal cancer may expect a positive impact as the treatment may extend the time until disease progression and an associated decrease in independence and ability to self-care. | | |
| 5.13 Consider any other groups and risk factors relevant to this project. | None identified | N/A | N/A |

6. HIA - How will the project impact on the health and wellbeing of people in Wales and help address inequalities in health?

Questions in this section relate to the impact on the overall health of individual people, and the impact on the population in Wales.

| How will the project impact on, or affect: | Potential positive and/or negative impacts and any particular groups affected | Recommendations for improvement/ mitigation | Actions taken (and who by) <i>Refer to where the mitigation is included in the document, as appropriate.</i> |
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| 6.1 People being able to access the service offered. | We do not expect a potential negative, or unequal, impact on people's ability to access the service offered. | N/A | N/A |
| 6.2 People being able to improve or maintain healthy lifestyles. | We do not expect a potential negative, or unequal, impact on people's ability to improve or maintain healthy lifestyles. | N/A | N/A |
| 6.3 People in terms of their income and employment status. | We do not expect a potential negative, or unequal, impact on the patient's employment status. | N/A | N/A |
| 6.4 People in terms of their use of the physical environment. | We do not expect a potential negative, or unequal, impact on people in terms of their use of the physical environment. | N/A | N/A |



| How will the project impact on, or affect: | Potential positive and/or negative impacts and any particular groups affected | Recommendations for improvement/ mitigation | Actions taken (and who by) <i>Refer to where the mitigation is included in the document, as appropriate.</i> |
|---|--|---|--|
| 6.5 People in terms of social and community influences on their health. | We do not expect a potential negative, or unequal, impact on people in terms of social and community influences on their health. | N/A | N/A |
| 6.6 People in terms of macro-economic, environmental and sustainability factors. | We do not expect a potential negative, or unequal, impact on people in terms of macroeconomic, environmental and sustainability factors. | The pharmaceutical industry aligns medicine manufacturing with sustainability practices and in line with the policy on climate change-international federation of pharmaceutical manufacturers association. | N/A |

7. Please fill in section 7.1 after completing the EqHIA, and fill in the action plan.

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| <p>7.1 Please summarize the potential positive and/or negative impacts of the project.</p> | <p>No potential negative impacts identified. We might expect a potential positive impact on people with colorectal cancer treated with panitumumab, and their families and carers.</p> |
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Action plan for mitigation or improvement and implementation

| | Action | Lead(s) | Timescale | Actions taken (<i>state who by</i>) |
|--|---|----------------|---|--|
| <p>7.2 What are the key actions identified as a result of completing the EqHIA?</p> | <ul style="list-style-type: none"> consult with clinical experts in Wales, with patient organisations, patients and carers in Wales (or the UK), and invite comments through the AWTTC website. AWTTC to prepare an Evidence Summary Report (ESR) One Wales Medicines Assessment Group (OWMAG) meet to consider and agree a recommendation. AWMSG meet to ratify OWMAG's recommendation about the use of panitumumab to treat colorectal cancer in Wales. | <p>AWTTC</p> | <p>Feb – Mar 2025</p> <p>Feb-Apr 2025</p> <p>May 2025</p> <p>May 2025</p> | |

| | Action | Lead(s) | Timescale | Actions taken (<i>state who by</i>) |
|---|--|----------------|------------------|--|
| 7.3 Is a more comprehensive Equalities Impact Assessment or Health Impact Assessment needed? | No | | | |
| 7.4 What are the next steps? | AWTTC to write an evidence summary report for consideration by the One Wales Medicines Assessment Group (OWMAG). | AWTTC | Mar 2025 | |
| 7.5 Review of project and EqHIA | | AWTTC | May 2026 | |

AWTTC's EqHIA template is adapted from the Cardiff & Vale University Health Board EHIA template.