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Welsh Health Specialised Services Committee (WHSSC)

Policy Position: Cytoreductive Surgery with Hyperthermic Intraperitoneal Chemotherapy for Peritoneal Carcinomatosis

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0.1	28/08/15	Policy approved by Management Group subject to addition of wording regarding approval process	1.0
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Relationship with other Policies and Service Specifications

This document should be read in conjunction with:

- All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR)
- Specialised Services Policy CP02: Hyperthermic Intraperitoneal Chemotherapy (HIPEC) and Cytoreductive Surgery (CRS) for treatment of Pseudomyxoma Peritonei

This written control document replaces all previous approved and draft versions

Policy Position Statement:
Cytoreductive Surgery with Hyperthermic Intraperitoneal Chemotherapy for Peritoneal Carcinomatosis

1. BACKGROUND

The WHSSC Prioritisation Group carried out an evidence evaluation in 2013 and made a recommendation not to fund HIPEC and CRS for colorectal cancer. In response to feedback obtained via the consultation process a further evaluation was conducted in 2014. This updated evaluation was reconsidered by the Prioritisation Panel in Oct 2014.
Key findings were:

- The quality of evidence supporting the use of HIPEC outside the setting of Pseudomyxoma Peritonei with low grade disease is weak
- Many of the case series suggesting benefit in patients with metastatic colorectal cancer include Pseudomyxoma Peritonei patients within their mixed cohorts which may positively skew results.
- The morbidity arising from the usually very extensive surgery followed by intraperitoneal chemotherapy is significant with all patients requiring postoperative care in an ITU. Overall morbidity rates for grade 3 to 4 toxicity vary between 14.8 – 76% with mortality rates of 4.8 – 12%.
- There is only one randomised control trial (Verwaal *et al*, 2003) of 103 patients which suggests possible early benefit. At 21 months 30 patients were alive in the HIPEC group compared with 20 in the standard treatment group however importantly standard treatment used lower doses of chemotherapy than is now in conventional use. Procedure related mortality was 8% and there was no difference in overall long term survival (8 years). Any benefit for HIPEC was seen in patients with more limited stage disease and complete resection with no difference in advanced disease.
- There is no reliable data on cost effectiveness.
- Accepting the case study data the calculated number needed to treat for HIPEC and cytoreductive surgery vs. standard chemotherapy to avoid 1 additional death at 7 months is 11.

The conclusions of the Prioritisation Panel (31st October 2014) were that there was a lack of conclusive data for clinical and cost effectiveness and the significant harms associated with the procedure. The Prioritisation Panel ranked HIPEC and CRS for the management of peritoneal cancer as a low priority and therefore should not be routinely funded.

NB: This policy statement is in divergence with the current commissioning position in England. In 2013 NHS England Clinical Commissioning Board published Cytoreductive Surgery for Peritoneal Carcinomatosis and concluded that 'for colorectal cancer there is clear long term survival benefit for selected patients'. This was taken from the Bazian review (2012) which states 'with the provision it should only be provided by surgeons with the experience and expertise ....it is effective and provides a significant benefit....'

Importantly this policy position does not take into account:

a) Consideration of the improvements in standard chemotherapy;
b) A critique of the quality of the evidence base (low grade evidence);
c) A cost effectiveness evaluation;

and did not go through relative prioritisation process.

2. SUMMARY OF POLICY POSITION

There is insufficient data on clinical and cost effectiveness to consider routine funding of HPIEC and CRS for the management of peritoneal carcinomatosis.

3. INDIVIDUAL PATIENT FUNDING REQUESTS: IMPLICATIONS OF THIS POLICY STATEMENT

IPFR Decision making factors	**Decision making factors related to HIPEC**
Clinical exceptionality Is the clinical presentation of the patient unusual/rare?	• Most patients present with abdominal pain, swelling or weight loss or on routine scans. • Evidence supporting the use in patients with limited disease is based on sub-group analysis and remains weak. • This is therefore unlikely to impact decision making
Evidence based considerations Does the treatment work?	• See above. The evidence base is weak and many of the case controlled studies predate newer Systemic Anti-Cancer Treatments which have been shown to prolong overall survival

What is the evidence base for clinical and cost effectiveness?	• The procedure costs £65,000 per patient. The very limited existing data assessing cost effectiveness is flawed • The WHSSC relative prioritisation process ranked this as low priority
Ethical considerations How has the decision been reached? Is the decision a compromise based on a balance between the evidence-based input and a value judgement?	Long term follow up in the only randomised control trial suggests that for the vast majority of patients this is a palliative procedure with a significant mortality and morbidity.
Conclusion: **The lack of a sufficient evidence base, cost and palliative nature of the procedures means that this will not be commissioned via WHSSC outside the setting of a randomised controlled trial.**	

4. RESPONSIBILITIES

In line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), the appropriate WHSSC officers will screen all IPFR applications in accordance with the All Wales Policy.