NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Health Technology Appraisal

Vinflunine for the second line treatment of transitional cell carcinoma of the urothelial tract

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of vinflunine monotherapy for the second line treatment of advanced or metastatic transitional cell carcinoma of the urothelial tract after failure of prior platinum-containing chemotherapy.

Background

The most common type of bladder cancer is transitional cell carcinoma (TCC; cancer that starts in the transitional cells which form the inner lining of the bladder, urethra, ureter, or renal pelvis). Most TCCs are papillary carcinomas which are superficial and well-differentiated, but some are sessile tumours which are more insidious, invade early, and metastasize. Other types of bladder cancers include squamous cell carcinoma (beginning in thin flat cells) and adenocarcinoma (beginning in cells which make and release mucus and other fluids). These types of bladder cancer arise as a result of chronic irritation and inflammation.

In 2006 more than 10,200 people were diagnosed with TCC. There are twice as many cases in men than women (7,300 vs. 3,000 new cases per year respectively), and 80% of cases occur in people aged 65 years and over. In 2006 there were 4,295 registered deaths from bladder cancer in England and Wales.

Patients with advanced TCC that has invaded the bladder wall or spread to the lymph nodes may receive treatment with surgery (radical cystectomy) and/or radiotherapy. Chemotherapy may be given before (neoadjuvant) or after surgery and/or radiotherapy in an attempt to improve cure rates. If the urothelial cancer is too advanced for surgery/radiotherapy or has recurred after these treatments, chemotherapy can be used to improve quality of life and survival. The most common first line chemotherapies in this setting are the platinum-based regimens cisplatin plus gemcitabine and carboplatin plus gemcitabine. Other platinum-containing regimens may also be used such as combination of methotrexate, vinblastine, doxorubicin, and cisplatin (MVAC) or gemcitabine plus either cisplatin or carboplatin. Chemotherapy such as gemcitabine and paclitaxel in combination may also be used. There are currently no agents specifically licensed in the UK for second line treatment of TCC.

The technology

Vinflunine (Javlor, Pierre Fabre) is a vinca alkaloid chemotherapeutic agent. It is administered by intravenous infusion and acts as a tubulin antagonist. Vinflunine has a marketing authorisation in the UK as monotherapy for the treatment of adult patients with advanced or metastatic TCC of the urothelium after failure of a prior platinum-containing chemotherapy regimen.

Intervention(s)	Vinflunine
Population(s)	Adults with advanced or metastatic TCC of urothelial tract after failure of prior platinum-containing chemotherapy.
Comparators	• best supportive care (defined as palliative radiotherapy, blood transfusion, analgesia, and symptomatic care)
Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • response rates • adverse effects of treatment • health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation.

Related NICE recommendations	Related Technology Appraisals: None. Related Interventional Procedures: Interventional Procedure No. 287, February 2009, Laparoscopic cystectomy. Related Clinical Guidelines: Cancer Service Guidance CSGUC, September 2002, Improving outcomes in urological cancers.