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Clinical Expert Summary
Lenvatinib (Lenvima®) 4 mg and 10 mg hard capsules

Lenvatinib (Lenvima®) for the treatment of adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI).

1. Existing guidelines

Reference was made to the guidelines of the American Thyroid Association (2015) and the British Thyroid Association (2014) which are used by multidisciplinary thyroid cancer team in Wales, in the absence of guidelines specific to Wales. Both guidelines recommend considering kinase inhibitor therapy for treating RAI-refractory differentiated thyroid cancer.

2. Disease prevalence/incidence

The number of patients who would potentially be eligible for treatment was estimated to be small, perhaps 2 to 5 patients per year.

3. Current treatment options

It was noted that patients who have radioiodine-refractory thyroid cancer have no alternative treatments available to them once their cancer stops responding to radioactive iodine treatment. It was reported that these patients are managed with best supportive care, which may include analgesia and palliative radiotherapy to symptomatic metastases.

4. Unmet needs

As stated above the only option for these radioiodine-refractory thyroid cancer patients is best supportive care. There are currently no clinical trials ongoing in Wales and therefore there are no alternative systemic oncological interventions available for radioiodine-refractory thyroid cancer patients in Wales. The clinical expert highlighted an inequity across the UK as sorafenib (Nexavar®) is currently available for patients in England and Scotland.

5. Knowledge of product in given indication

It was stated that only patients with radioiodine-refractory differentiated thyroid cancer would be eligible for consideration for lenvatinib (Lenvima®) treatment and only when they have evidence of clinically significant or symptomatic disease progression. Patients would need to have a WHO performance status of 0–2 and have no co-morbidities or concomitant medications that would preclude treatment with lenvatinib.

In addition, it was noted that patients would need to be assessed by an oncologist with experience of treating thyroid cancer, and that lenvatinib treatment would need to be started and managed in a cancer centre. Monitoring for toxicity would be done during the first phase of lenvatinib treatment; lenvatinib would be discontinued if significant or unmanageable toxicity occurred, or if there was evidence of significant disease progression during treatment. Lenvatinib treatment would be continued for as long as there was clinical evidence of its benefit to the patient.

It should be noted that one expert(s) involved in compiling this response declared a personal specific interest in relation to lenvatinib for the indication under consideration.