



**Final Appraisal Recommendation**

Advice No: 1017 – June 2017

**Ivacaftor (Kalydeco<sup>®</sup>) 150 mg film-coated tablets**

**Submission by Vertex Pharmaceuticals (Europe) Ltd**

**Recommendation of AWMSG**

Ivacaftor (Kalydeco<sup>®</sup>) is recommended for restricted use within NHS Wales for the treatment of patients with cystic fibrosis (CF) aged 18 years and older who have an *R117H* mutation in the CF transmembrane conductance regulator (*CFTR*) gene.

This recommendation will apply only when people are treated in line with the relevant Welsh clinical access policy.

This recommendation applies only in circumstances where the approved Wales Patient Access Scheme (WPAS) is utilised or where the list/contract price is equivalent or lower than the WPAS price.

**Additional note(s):**

- Please refer to the Summary of Product Characteristics for the full licensed indication.
- AWMSG considered that ivacaftor (Kalydeco<sup>®</sup>) satisfied the AWMSG criteria for ultra-orphan status.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 2680), which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

This recommendation has been ratified by Welsh Government and will be considered for review every three years.

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All Wales Medicines Strategy Group Final Appraisal Recommendation – 1017:  
Ivacaftor (Kalydeco<sup>®</sup>) 150 mg film-coated tablets. June 2017.



NICE has accredited the process used by the All Wales Medicines Strategy Group (AWMSG) to produce its final appraisal recommendation. Accreditation is valid for 5 years from October 2011. More information on accreditation can be viewed at [www.evidence.nhs.uk](http://www.evidence.nhs.uk).

For full details on our accreditation visit: [www.nice.org.uk/accreditation](http://www.nice.org.uk/accreditation).