pancreatitis · paraneoplastic syndrome · peripheral ischaemia · polymyalgia rheumatica · psychiatric disorder · pulmonary oedema · renal failure · renal tubular acidosis · respiratory disorders · sepsis · severe cutaneous adverse reactions (SCARs) · syncope · systemic inflammatory response syndrome · thrombocytopenia · tremor · tumour lysis syndrome · vascular disorders · vasculitis

- **Rare or very rare** Myasthenia gravis · proteinuria · thyroiditis
- **Frequency not known** Cytomegalovirus infection reactivation

SIDE-EFFECTS, FURTHER INFORMATION A corticosteroid can be used after starting ipilimumab, to treat immune-related reactions.

- **CONCEPTION AND CONTRACEPTION** Use effective contraception.
- **PREGNANCY** Manufacturer advises avoid unless potential benefit outweighs risk—toxicity in *animal* studies.
- **BREAST FEEDING** Manufacturer advises avoid—present in milk in *animal* studies.
- **HEPATIC IMPAIRMENT** Manufacturer advises caution if bilirubin greater than 3 times upper limit of normal range or if transaminases equal to or greater than 5 times upper limit of normal range (limited information available).
- **MONITORING REQUIREMENTS**
  - Manufacturer advises monitor liver function tests and thyroid function prior to initiation of treatment and before each dose.
  - Manufacturer advises monitor for signs or symptoms of immune-related side-effects and gastrointestinal perforation—consult product literature.
- **DIRECTIONS FOR ADMINISTRATION** Manufacturer advises for *intravenous infusion*, give undiluted or dilute to a concentration of 1–4 mg/mL with Glucose 5% *or* Sodium Chloride 0.9%; give over 90 minutes.
- **PRESCRIBING AND DISPENSING INFORMATION** Infusion-related side-effects have been reported; premedication with paracetamol and an antihistamine is recommended.
- **HANDLING AND STORAGE** Manufacturer advises store in a refrigerator (2–8 °C) and protect from light—consult product literature for further information regarding storage conditions outside refrigerator and after preparation of the infusion.
- **NATIONAL FUNDING/ACCESS DECISIONS**

NICE decisions

- **Ipilimumab for previously treated advanced (unresectable or metastatic) melanoma (December 2012)** NICE TA268
  Ipilimumab (*Yervoy*®) is recommended as an option for the treatment of advanced (unresectable or metastatic) melanoma in adults who have received prior therapy, only if the manufacturer provides ipilimumab with the discount agreed in the patient access scheme.
  www.nice.org.uk/guidance/ta268
- **Ipilimumab for previously untreated advanced (unresectable or metastatic) melanoma (July 2014)** NICE TA319
  Ipilimumab (*Yervoy*®) is recommended, within its marketing authorisation, as an option for treating adults with previously untreated advanced (unresectable or metastatic) melanoma, only if the manufacturer provides ipilimumab with the discount agreed in the patient access scheme.
  www.nice.org.uk/guidance/ta319
- **Nivolumab in combination with ipilimumab for treating advanced melanoma (July 2016)** NICE TA400
  Nivolumab in combination with ipilimumab (*Yervoy*®) is recommended, within its marketing authorisation, as a treatment option for advanced (unresectable or metastatic) melanoma in adults, only if the manufacturer provides ipilimumab with the discount agreed in the patient access scheme.
  www.nice.org.uk/guidance/ta400
- **Nivolumab with ipilimumab for untreated advanced renal cell carcinoma (May 2019)** NICE TA581
  Nivolumab in combination with ipilimumab (*Yervoy*®) is recommended for use within the Cancer Drugs Fund as an option for adults with untreated advanced renal cell carcinoma that is intermediate- or poor-risk as defined in the International Metastatic Renal Cell Carcinoma Database Consortium criteria. It is recommended only if the conditions in the managed access agreement for nivolumab with ipilimumab are followed.
  Patients whose treatment was started within the NHS before this guidance was published should have the option to continue treatment, without change to their funding arrangements, until they and their NHS clinician consider it appropriate to stop.
  www.nice.org.uk/guidance/ta581

Scottish Medicines Consortium (SMC) decisions

SMC No. 779/12
The *Scottish Medicines Consortium* has advised (April 2013) that ipilimumab (*Yervoy*®) is accepted for use within NHS Scotland for the treatment of advanced (unresectable or metastatic) melanoma in adults who have received prior therapy. This advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.

SMC No. 997/14
The *Scottish Medicines Consortium* has advised (November 2014) that ipilimumab (*Yervoy*®) is accepted for use within NHS Scotland for the first-line treatment of advanced (unresectable or metastatic) melanoma in adults. This advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug.

Solution for infusion

ELECTROLYTES: May contain Sodium

- **Yervoy** (Bristol-Myers Squibb Pharmaceuticals Ltd)
  Ipilimumab 5 mg per 1 ml Yervoy 50mg/10ml concentrate for solution for infusion vials | 1 vial PoM £3,750.00 (Hospital only)
  Yervoy 200mg/40ml concentrate for solution for infusion vials | 1 vial PoM £15,000.00 (Hospital only)

Mogamulizumab

17-Apr-2020

- **DRUG ACTION** Mogamulizumab is a monoclonal antibody, which binds to the CCR4 receptor, thereby potentiating an immune response to cancer cells.
- **INDICATIONS AND DOSE**

Mycosis fungoides (initiated by a specialist) | Sézary syndrome (initiated by a specialist)

- BY INTRAVENOUS INFUSION
- Adult: 1 mg/kg every week on days 1, 8, 15 and 22 of the first 28-day cycle, followed by 1 mg/kg every 2 weeks on days 1 and 15 of subsequent 28-day cycles, dose to be administered within 2 days of the scheduled day, for treatment interruption or discontinuation due to side-effects and infusion-related reactions—consult product literature

- **CAUTIONS** Patients may need pre-medication to minimise infusion-related reactions · risk factors for cardiac disorders · risk of serious infection and/or viral reactivation such as hepatitis B · risk of transplant-related complications