

## Active substances set

**Search phrase:** Colon and rectum cancer

Below you will find a list of active substances registered by the European Medical Agency (EMA) in the last 15 years, recommended by the European Society of Clinical Oncology (ESMO) and their reimbursement status in the country.

### Colon and rectum cancer

#### Ramucirumab

Ramucirumab, in combination with FOLFIRI (irinotecan, folinic acid, and 5-fluorouracil), is indicated for the treatment of adult patients with metastatic colorectal cancer (mCRC) with disease progression on or after prior therapy with bevacizumab, oxaliplatin and a fluoropyrimidine.

 **NO REIMBURSEMENT**  
 **ESMO**

#### Encorafenib

Encorafenib is indicated in combination with cetuximab, for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation, who have received prior systemic therapy.

 **NO REIMBURSEMENT**  
 **ESMO**

#### Ipilimumab

Ipilimumab in combination with nivolumab is indicated for the treatment of adult patients with mismatch repair deficient or microsatellite instability-high metastatic colorectal cancer after prior fluoropyrimidine-based combination chemotherapy.

 **NO REIMBURSEMENT**  
 **ESMO**

#### Nivolumab

Nivolumab in combination with ipilimumab is indicated for the treatment of adult patients with mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) metastatic colorectal cancer (CRC) after prior fluoropyrimidine-based combination chemotherapy.

 **NO REIMBURSEMENT**  
 **ESMO**

**Tegafur /  
gimeracil /  
oteracil**

Tegafur / Gimeracil / Oteracil is indicated in adults as monotherapy or in combination with oxaliplatin or irinotecan, with or without bevacizumab, for the treatment of patients with metastatic colorectal cancer for whom it is not possible to continue treatment with another fluoropyrimidine due to hand-foot syndrome or cardiovascular toxicity that developed in the adjuvant or metastatic setting.



**Larotrectinib**

Larotrectinib as monotherapy is indicated for the treatment of adult and paediatric patients with solid tumours that display a Neurotrophic Tyrosine Receptor Kinase (NTRK) gene fusion, - who have a disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity, and - who have no satisfactory treatment options.



**Aflibercept**

Aflibercept in combination with irinotecan/5-fluorouracil/folinic acid (FOLFIRI) chemotherapy is indicated in adults with metastatic colorectal cancer (MCRC) that is resistant to or has progressed after an oxaliplatin-containing regimen.



**Regorafenib**

Regorafenib is indicated as monotherapy for the treatment of adult patients with metastatic colorectal cancer (CRC) who have been previously treated with, or are not considered candidates for, available therapies. These include fluoropyrimidine-based chemotherapy, an anti-VEGF therapy and an anti-EGFR therapy.



**Trifluridine /  
tipiracil  
hydrochloride**

Trifluridine / Tipiracil Hydrochloride is indicated in combination with bevacizumab for the treatment of adult patients with metastatic colorectal cancer (CRC) who have received two prior anticancer treatment regimens including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-VEGF agents, and/or anti-EGFR agents. Trifluridine / Tipiracil Hydrochloride is indicated as monotherapy for the treatment of adult patients with metastatic colorectal cancer who have been previously treated with, or are not considered candidates for, available therapies including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-VEGF agents, and anti-EGFR agents.



## Entrectinib

Entrectinib as monotherapy is indicated for the treatment of adult and paediatric patients 12 years of age and older with solid tumours expressing a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, - who have a disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity, and - who have not received a prior NTRK inhibitor - who have no satisfactory treatment options.

- ✓ FULL REIMBURSEMENT
- ✓ ESMO

---

## Pembrolizumab

Pembrolizumab as monotherapy is indicated for adults with microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer in the following settings:  
- first-line treatment of metastatic colorectal cancer; - treatment of unresectable or metastatic colorectal cancer after previous fluoropyrimidine-based combination therapy.

- ✓ FULL REIMBURSEMENT
- ✓ ESMO