

Active substances set

Search phrase: Malignant prostate 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.

Malignant prostate cancer

Olaparib

Olaparib is indicated: - as monotherapy for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC) and BRCA1/2-mutations (germline and/or somatic) who have progressed following prior therapy that included a new hormonal agent. - in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with mCRPC in whom chemotherapy is not clinically indicated.

 **NO REIMBURSEMENT**

 **ESMO**

Abiraterone

Abiraterone is indicated with prednisone or prednisolone for: - the treatment of newly diagnosed high risk metastatic hormone sensitive prostate cancer (mHSPC) in adult men in combination with androgen deprivation therapy (ADT) - the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated - the treatment of mCRPC in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen.

 **REIMBURSEMENT WITH RESTRICTIONS**

 **ESMO**

Enzalutamide

Enzalutamide is indicated: - as monotherapy or in combination with androgen deprivation therapy for the treatment of adult men with high-risk biochemical recurrent (BCR) non-metastatic hormone-sensitive prostate cancer (nmHSPC) who are unsuitable for salvage-radiotherapy. - in combination with androgen deprivation therapy for the treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC). - for the treatment of adult men with high-risk non-metastatic castration-resistant prostate cancer (CRPC). - for the treatment of adult men with metastatic CRPC who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated. - for the treatment of adult men with metastatic CRPC whose disease has progressed on or after docetaxel therapy.

 **REIMBURSEMENT WITH RESTRICTIONS**

 **ESMO**

Apalutamide

Apalutamide is indicated: - in adult men for the treatment of non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease. - in adult men for the treatment of metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT).

 **REIMBURSEMENT WITH RESTRICTIONS**

 **ESMO**

Darolutamide

Darolutamide is indicated for the treatment of adult men with - non-metastatic castration resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease. - metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel and androgen deprivation therapy.

 **REIMBURSEMENT WITH RESTRICTIONS**

 **ESMO**

Niraparib / abiraterone acetate

Niraparib / abiraterone acetate is indicated with prednisone or prednisolone: - in combination with androgen deprivation therapy (ADT) for the treatment of adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) and BRCA 1/2 mutations (germline and/or somatic). - for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC) and BRCA 1/2 mutations (germline and/or somatic) in whom chemotherapy is not clinically indicated.

 **REIMBURSEMENT WITH RESTRICTIONS**

 **ESMO**

Talazoparib

Talazoparib is indicated in combination with enzalutamide for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated.

 **REIMBURSEMENT WITH RESTRICTIONS**

 **ESMO**

Cabazitaxel

Cabazitaxel in combination with prednisone or prednisolone is indicated for the treatment of adult patients with metastatic castration resistant prostate cancer previously treated with a docetaxel-containing regimen.

 **FULL REIMBURSEMENT**

 **ESMO**