# Active substances set

**Search phrase:** Multiple myeloma and plasma cell neoplasms

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.

## Multiple myeloma and plasma cell neoplasms

| | | |
|---|---|---|
| **Ibrutinib** | Ibrutinib as a single agent is indicated for the treatment of adult patients with Waldenström's macroglobulinaemia (WM) who have received at least one prior therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy. Ibrutinib in combination with rituximab is indicated for the treatment of adult patients with WM. | NO REIMBURSEMENT<br>ESMO |
| **Selinexor** | Selinexor is indicated: - in combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. - in combination with dexamethasone for the treatment of multiple myeloma in adult patients who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, two immunomodulatory agents and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy. | NO REIMBURSEMENT<br>ESMO |
| **Idecabtagene vicleucel** | Idecabtagene vicleucel is indicated for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody and have demonstrated disease progression on the last therapy. | NO REIMBURSEMENT<br>ESMO |

| | | |
|---|---|---|
| **Ciltacabtagene autoleucel** | Ciltacabtagene autoleucel is indicated for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least one prior therapy, including an immunomodulatory agent and a proteasome inhibitor, have demonstrated disease progression on the last therapy, and are refractory to lenalidomide. | NO REIMBURSEMENT<br>ESMO |
| **Linvoseltamab** | Linvoseltamab is indicated as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least 3 prior therapies, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody, and have demonstrated disease progression on the last therapy. | NO REIMBURSEMENT<br>ESMO |
| **Carfilzomib** | Carfilzomib in combination with daratumumab and dexamethasone, with lenalidomide and dexamethasone, or with dexamethasone alone is indicated for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. | REIMBURSEMENT WITH RESTRICTIONS<br>ESMO |
| **Elotuzumab** | Elotuzumab is indicated in combination with lenalidomide and dexamethasone for the treatment of multiple myeloma in adult patients who have received at least one prior therapy. Elotuzumab is indicated in combination with pomalidomide and dexamethasone for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on the last therapy. | REIMBURSEMENT WITH RESTRICTIONS<br>ESMO |

| | | |
|---|---|---|
| **Daratumumab** | Multiple myeloma Daratumumab is indicated: - in combination with lenalidomide and dexamethasone or with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. - in combination with bortezomib, lenalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant. - in combination with bortezomib, thalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant. - in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. - in combination with pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received one prior therapy containing a proteasome inhibitor and lenalidomide and were lenalidomide-refractory, or who have received at least two prior therapies that included lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or after the last therapy. - as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy. Smouldering multiple myeloma Daratumumab as monotherapy is indicated for the treatment of adult patients with smouldering multiple myeloma at high risk of developing multiple myeloma. | REIMBURSEMENT WITH RESTRICTIONS<br>ESMO |
| **Ixazomib** | Ixazomib in combination with lenalidomide and dexamethasone is indicated for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. | REIMBURSEMENT WITH RESTRICTIONS<br>ESMO |

| | | |
|---|---|---|
| **Isatuximab** | Isatuximab is indicated: - in combination with pomalidomide and dexamethasone, for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on the last therapy. - in combination with carfilzomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. - in combination with bortezomib, lenalidomide, and dexamethasone, for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. | REIMBURSEMENT WITH RESTRICTIONS<br>ESMO |
| **Teclistamab** | Teclistamab is indicated as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy. | REIMBURSEMENT WITH RESTRICTIONS<br>ESMO |
| **Pomalidomide** | Pomalidomide in combination with bortezomib and dexamethasone is indicated in the treatment of adult patients with multiple myeloma who have received at least one prior treatment regimen including lenalidomide. Pomalidomide in combination with dexamethasone is indicated in the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy. | FULL REIMBURSEMENT<br>ESMO |
| **Zanubrutinib** | Zanubrutinib as monotherapy is indicated for the treatment of adult patients with Waldenström’s macroglobulinaemia (WM) who have received at least one prior therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy. | FULL REIMBURSEMENT<br>ESMO |
| **Talquetamab** | Talquetamab is indicated as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least 3 prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy. | FULL REIMBURSEMENT<br>ESMO |

| | | |
|---|---|---|
| **Elranatamab** | Elranatamab is indicated as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy. | FULL REIMBURSEMENT<br>ESMO |
| **Belantamab mafodotin** | Belantamab mafodotin is indicated in adults for the treatment of relapsed or refractory multiple myeloma: • in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy; and • in combination with pomalidomide and dexamethasone in patients who have received at least one prior therapy including lenalidomide. | FULL REIMBURSEMENT<br>ESMO |