Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on the discontinuation of a benefit assessment procedure according to Section 35a SGB V on Brentuximab vedotin (reassessment of an orphan drug after exceeding the EUR 30 million turnover limit; new therapeutic indication: Hodgkin lymphoma, CD30+, stage III, first-line)

of 18 July 2024

The Federal Joint Committee (G-BA) decided the following at its session on 18 July 2024:

I. The following benefit assessment procedures (reassessment of an orphan drug after exceeding the EUR 30 million turnover limit) are discontinued in accordance with Section 35a SGB V for the proprietary medicinal product Adcetris with the active ingredient brentuximab vedotin in the therapeutic indications

- Brentuximab vedotin is indicated for adult patients with previously untreated CD30+ Stage III or IV Hodgkin lymphoma (HL) in combination with doxorubicin, vinblastine and dacarbazine (AVD) (see sections 4.2 and 5.1).
- Brentuximab vedotin is indicated for the treatment of adult patients with CD30+ HL at increased risk of relapse or progression following autologous stem cell transplant (ASCT) (see section 5.1).
- Brentuximab vedotin is indicated for the treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma (HL):
  1. following ASCT, or
  2. following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option.
- Brentuximab vedotin in combination with cyclophosphamide, doxorubicin and prednisone (CHP) is indicated for adult patients with previously untreated systemic anaplastic large cell lymphoma (sALCL) (see section 5.1).
- Brentuximab vedotin is indicated for the treatment of adult patients with relapsed or refractory sALCL.
- Brentuximab vedotin is indicated for the treatment of adult patients with CD30+ cutaneous T-cell lymphoma (CTCL) after at least 1 prior systemic therapy (see section 5.1).

.

II. The benefit assessment procedure for the proprietary medicinal product Adcetris with the active ingredient brentuximab vedotin in the therapeutic indication "is indicated for adult patients with previously untreated CD30+ Stage III Hodgkin lymphoma (HL) in combination

with doxorubicin, vinblastine and dacarbazine (AVD)", which was temporarily suspended by resolution of 18 January 2024, is discontinued.

III. The resolution will enter into force on the day of its publication on the website of the G-BA on 18 July 2024.

The justification to this resolution will be published on the website of the G-BA at www.g-ba.de.

Berlin, 18 July 2024

Federal Joint Committee (G-BA)
in accordance with Section 91 SGB V
The Chair

Prof. Hecken