

arzneimittel



## Nivolumab (Opdivo®)

Nierenzellkarzinom (Hypernephrom) » + Ipilimumab (Yervoy®) »  
fortgeschritten, Erstlinie, intermediäres Risiko

Empfehlungen der Fachgesellschaft zum Einsatz neuer Arzneimittel

## **Herausgeber**

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## **Quelle**

[www.onkopedia.com](http://www.onkopedia.com)

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# Nivolumab (Opdivo®)

**Dokument:** Fact Sheet

**Spezifizierung:** Nierenzellkarzinom (Hypernephrom) » + Ipilimumab (Yervoy®) » fortgeschritten, Erstlinie, intermediäres Risiko

**Stand:** Mai 2020

## 1 Nivolumab + Ipilimumab, RCC, advanced, first line, intermediate risk

### Nivolumab + Ipilimumab, RCC, advanced, first line, intermediate risk

onkopedia				Facts	Appraisal	EU Approval 2019																																																																							
<b>Parameter</b>	<b>Results<sup>6</sup></b>	<b>HR<sup>9</sup></b>	<b>p value</b>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;">Evidence (LoE)</td> <td style="width: 5%;">5</td><td style="width: 5%;">4</td><td style="width: 5%;">3b</td><td style="width: 5%;">3a</td><td style="width: 5%;">2c</td><td style="width: 5%;">2b</td><td style="width: 5%;">2a</td><td style="width: 5%;">1b</td><td style="width: 5%;">1a</td> </tr> <tr> <td style="text-align: center;">Clinical benefit (ESMO MCBS)</td> <td style="text-align: center;">1</td><td style="text-align: center;">2</td><td style="text-align: center;">3</td><td style="text-align: center;">4</td><td style="text-align: center;">5</td> <td colspan="4"></td> </tr> <tr> <td colspan="10"> <div style="display: flex; justify-content: space-between;"> <span style="color: blue;">■</span> curative                             <span style="color: yellow;">■</span> non-curative                         </div> </td> </tr> <tr> <td colspan="10"><b>Additional benefits (G-BA)</b></td> </tr> <tr> <td colspan="10" style="text-align: center;"> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;"></td> <td style="width: 15%;">lower</td> <td style="width: 15%;">proven</td> <td style="width: 15%;">not quantifiable</td> <td style="width: 15%;">not minor</td> <td style="width: 15%;">considerable</td> <td style="width: 15%;">major</td> </tr> <tr> <td style="text-align: center;">intermediate risk (IMDC)<sup>19</sup></td> <td></td><td></td><td></td><td></td><td style="background-color: black;"></td><td></td> </tr> <tr> <td style="text-align: center;">high risk (IMDC)<sup>20</sup></td> <td></td><td></td><td></td><td></td><td style="background-color: black;"></td><td></td> </tr> </table> </td> </tr> </table>			Evidence (LoE)	5	4	3b	3a	2c	2b	2a	1b	1a	Clinical benefit (ESMO MCBS)	1	2	3	4	5					<div style="display: flex; justify-content: space-between;"> <span style="color: blue;">■</span> curative                             <span style="color: yellow;">■</span> non-curative                         </div>										<b>Additional benefits (G-BA)</b>										<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;"></td> <td style="width: 15%;">lower</td> <td style="width: 15%;">proven</td> <td style="width: 15%;">not quantifiable</td> <td style="width: 15%;">not minor</td> <td style="width: 15%;">considerable</td> <td style="width: 15%;">major</td> </tr> <tr> <td style="text-align: center;">intermediate risk (IMDC)<sup>19</sup></td> <td></td><td></td><td></td><td></td><td style="background-color: black;"></td><td></td> </tr> <tr> <td style="text-align: center;">high risk (IMDC)<sup>20</sup></td> <td></td><td></td><td></td><td></td><td style="background-color: black;"></td><td></td> </tr> </table>											lower	proven	not quantifiable	not minor	considerable	major	intermediate risk (IMDC) <sup>19</sup>							high risk (IMDC) <sup>20</sup>						
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RR <sup>2</sup>	30 vs 42		p = 0.0014																																																																										
PFS <sup>3</sup>	9.8 vs 12.5	0.89	n.s. <sup>10</sup>																																																																										
OS <sup>5</sup>	34.8 vs n.r.	0.697	p = 0.0025																																																																										
SAE <sup>7</sup>	63 vs 46																																																																												
<b>Patients</b>	advanced/metastatic, intermediate risk																																																																												
<b>Trial</b>	CheckMate 214, phase 3																																																																												
<b>Randomisation</b>	1 : 1																																																																												
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<b>New Therapy</b>	Nivolumab + Ipilimumab																																																																												
<b>Control</b>	Sunitinib																																																																												
<b>Publication</b>	DOI:10.1056/NEJMoa1712126																																																																												

Legende:

<sup>1</sup> N - number of patients

<sup>2</sup> RR - remission rate, in %

<sup>3</sup> PFS - progression-free survival in months

<sup>5</sup> OS - overall survival in months

<sup>7</sup> SAE - serious adverse events, CTCAE grade 3/4

<sup>8</sup> results for control, results for new therapy

<sup>9</sup> hazard ratio for new therapy

<sup>10</sup> n. s. not significant

<sup>19</sup> International Metastatic Renal-Cell Carcinoma Database Consortium Score

<sup>20</sup> International Metastatic Renal-Cell Carcinoma Database Consortium Score