Market Access and HEOR Support
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Sample Questions for Payer Interviews in EU3, Germany

For Current Therapies

Q1. What sort of impact has the Gesetz zur Stärkung der Arzneimittelversorgung in der GKV (AMVSG; Act to Strengthen Pharmaceutical Supply in the Statutory Health Insurance System) had on market access for [[XX]] therapies?

- Will it have any impact on prescribing of these drugs?

Q2. Do [[XX]] patients represent a substantial burden to the German healthcare system? Do you think there are many patients with [[XX]] that go undiagnosed in Germany, or is there a good screening program in place?

- To what extent are the costs of [[XX]] treatment reimbursed for patients?
- Will it become harder for patients to have access to therapies to treat [[XX]] in the future?

Q3. What treatment guidelines do physicians follow for [[XX]] (i.e. national guidelines, regional guidelines, local/hospital guidelines)?

- How strictly must physicians adhere to guidelines to ensure reimbursement for [[XX]] patients?

Q4. It is our understanding that Richtgrößen have been phased out in some regions of Germany and replaced by mostly-similar regional agreements.

- Is the prescribing of current therapies impacted by Richtgrößen or similarly-constructed regional agreements?
- Is it difficult for physicians to prescribe these therapies without exceeding their budget?

Q5. To what extent are physician prescribing practices monitored? At which level does the monitoring take place (national, regional, local/hospital) and how is it done?

- Are there any penalties for non adherence?
- How do you think the monitoring of physician prescribing practices may change over the next few years?

Q6. In which setting are most [[XX]] patients treated? Does funding for [[XX]] treatment come from the global hospital budget or directly from the Krankenkassen?

Q7. How important are [[XX]] Zusatzengelte (ZE) status funding mechanisms for the prescription and use of these therapies for [[XX]]?

- How about [[XX]] Neue Untersuchungs und Behandlungsmethoden-1 (NUB-1; New methods of Examination and Treatment-1) status?
- Are drugs without NUB-1 or ZE status prescribed less frequently?

Q8. [[XX]] received a No Added Benefit rating over [[XX]] for [[XX]] patients.

- What impact does a "no added benefit" rating have on physician prescribing?
- How about on reimbursement, given the ruling on pricing in no-added benefit indications?

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Q9. **What do you think is the average discount to list price that hospitals are able to get on [[XX]] therapies?**

- **To what extent do these discounts affect the inclusion of these therapies in hospital formularies?**
- **How importantly does cost factor into physicians' first-line therapy choice?**

Q10. **Given Germany's strong use of both generics and biosimilars, what policies are currently in place to encourage the prescribing of biosimilar therapies?**

- **What will be the impact of biosimilar availability for new costly branded [[XX]] therapies?**
- **Will physicians be required to prescribe biosimilars over branded [[XX]] therapies?**

For Emerging Therapies

Q1. **What kind of data is most important for emerging [[XX]] therapies to demonstrate an added benefit to IQWiG and the G-BA?**

- **Will they need head-to-head data? What would they have to show in terms of safety or efficacy to demonstrate additional benefit over current therapies?**
- **What would be the best comparator to use for a new [[XX]] agent?**
- **Two emerging therapies [[XX]] offer extended dosing compared to [[XX]]. How important is dosing frequency from a payer perspective, assuming that efficacy and safety are at least comparable?**
- **How important is pharmacoeconomic data for the drug evaluation?**
- **How important is real-world data (RWD)? Do you anticipate increased use for RWD in the pricing and reimbursement process in the future?**

Q2. **What are your expectations for the added benefit assessment for each of the therapies, presuming each one gains marketing authorization in Europe?**

- **Which one of the emerging therapies do you think has the greatest potential for a high price?**

Q3. **Do you anticipate any payer-imposed prescribing, dispensation, and/or monitoring guidelines that could restrict the use of any of these drugs?**

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For Emerging Therapies…

Q4. **Do you expect any of the emerging therapies to be subject to managed entry agreements (MEAs), such as risk-sharing or price-volume agreements?**

- **Is there the potential for increased use of MEAs in Germany in the future? Is there a preferred design for an MEA in Germany?**

Q5. **Do you anticipate any emerging therapy to be granted NUB-1 status?**

- **How strict are the conditions for granting NUB-1 status for emerging therapies specifically?**
- **What attributes would they have to have to attain NUB-1 status?**

Q6. **Are there are upcoming healthcare reforms or changes in the pricing and reimbursement system that we have not already discussed?**

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