Some credentialing factors that should be considered when evaluating a provider’s eligibility for a contract include—

- Willingness to accept and comply with MBP or PBM contract terms and conditions
- Appropriate license for the services required, updated as necessary
- Access for beneficiaries – location and hours of service
- Physical facility – necessary space for dispensing and counseling, cleanliness and neatness, and storage conditions meeting national regulatory standards for medicines (including cold storage)
- Dispensing equipment and practices meeting professional standards
- Physical security, including capacity to secure and effectively control medicines that require special handling, including controlled substances
- Staffing standards – professional staff with required education and license, support staff with appropriate training, quantity of professional and support staff needed to manage the workload associated with serving MBP members
- Procurement standards – sourcing of high-quality medicines meeting standards of the national drug regulatory authority, all with required product registration
- Inventory management capacity, including prior performance reports and extent of past experiences with stock-outs
- Process for managing prescription records and patient profiles
- Internal DUR process and capacity to support MBP utilization review processes
- Patient services provided including counseling
- Quality management and improvement programs
- Accounting and auditing procedures
- Ability to manage the claims process required by the MBP
• Computerized systems, if any, and compatibility with MBP claims process (if MBP uses automated systems)
  • Willingness to offer discounts on dispensing fees and markups on medicine cost (if discounts are allowable under national pricing regulations)
  • Past performance in other programs or networks

Typical contract terms will cover the following issues*—

• General and specific responsibilities and rights of the service provider
• Credentialing and licensing requirements including those covering physical facilities, patient access, and staffing
• Insurance – provider will maintain liability coverage as required for the profession in the national laws and regulations (or as stipulated by the MBP if no applicable law)
• Professional services and standards and exercise of professional judgment
• Requirements for verification of beneficiary eligibility
• Collection of user fees – co-payments or co-insurance (if required)
• Limitation on collections – no charging to beneficiaries beyond collecting the co-pays or co-insurance stipulated by the MBP for covered services and medicines/health commodities
• Documentation of receipt of medicines by beneficiaries
• Documentation of patient counseling (as required)
• Manual maintenance of patient medication profiles by contract pharmacists and dispensers to facilitate DUR, if automated patient profiles are not available (may be required by MBP)
• Record retention (prescription records, patient profiles, and copies of prescriptions)
• Electronic communication standards (if applicable)
• Compliance with the MBP’s drug formulary or preferred drug list
• Compliance with policies on dispensing generic drugs or “lowest cost” alternatives as applicable
• Policies regarding caps on numbers of prescriptions or dispensing quantities (if applicable)
• Authorization process for requests or prescriptions that are non-standard or may violate MBP standards
• Compliance with MBP utilization review procedures, in addition to providing professional review of prescriptions according to national standards for the profession
• Compliance and cooperation with audits as may be required by the MBP or PBM, including providing access to all relevant records
• Non-discrimination – all eligible members will be served equally and be provided medicines and services unless professional judgment dictates

otherwise for a specific patient, in which case the prescriber or the MBP will be notified

▪ Cooperation and compliance with member complaint procedures stipulated by the MBP
▪ Compliance with claims submission and adjudication process
▪ Contract pricing terms for dispensing fees and medicines (ingredient costs), including any tiered or discount terms applying to different medicine categories
▪ Standard process for payment of claims and terms of payment and timing of payment process
▪ Payment process, terms and timing for out of network claims
▪ Payment process, terms and timing for non-standard claims requiring authorization
▪ Prior authorization process and retrospective authorization process if applicable
▪ Confidentiality policy concerning information provided by MBP or PBM company
▪ Confidentiality of patient information
▪ Intellectual property rights for products, terms, trademarks, and information materials provided by or owned by MBP or PBM company
▪ Incentives for participation or compliance with specific MBP programs
▪ Penalties for provider’s non-compliance with contract terms
▪ Financial penalties including requirement for reimbursement for paid claims identified as fraudulent
▪ Suspension or termination of network participation initiated by MBP
▪ Termination of network participation, initiated by provider
Key selection criteria include the following:\(^2\)

- Capacity to provide required medicines and prescription services to target beneficiaries within desired lead times
- Efficiency of claims handling processes and ability to interface with provider and MBP systems
- Capacity to manage communications with beneficiaries and service providers, including educational outreach programs and call centers to respond to provider or beneficiary questions
- Access to technology to support claims management, management reports, utilization review and related audits, and communications/outreach programs
- Capacity to develop and manage the provider network including specialty and mail order services if appropriate for the setting
- Capacity to support effective formulary development and management to assure adherence
- Capacity to manage conflict-of-interest policies
- Capacity to manage and support utilization review programs
- Capacity to negotiate discounts and rebates with pharmaceutical suppliers
- Capacity to respond to queries and complaints from providers and beneficiaries and call centers to support responsiveness
- Capacity to prevent, detect, and correct medication errors
- Capacity to support clinical programs, such as medication therapy management and disease managements
- Capacity to detect potential fraud and abuse and to manage interventions to correct problems that are identified
- Flexibility of system or capacity to support multiple plans with complex rules
- Quality assurance and quality management
▪ Robust information technology systems
▪ Comprehensive reporting
▪ Clinical support
▪ Plan design consulting
▪ Pharmacy contracting and performance management
▪ Development of a comprehensive medicine product database for the country

Once a PBM is selected the contract should specify—
▪ The roles, authorities and responsibilities of the PBM and the MBP in the medicines benefit plan
▪ The specific tasks and services to be provided by the PBM
▪ Payment terms for each of the services to be provided, including any penalties for poor performance
▪ Performance targets, which might include indicators such as fill rates, turnaround times, generic substitution rates, formulary adherence, rebate levels, average and total prescription costs, beneficiary and provider satisfaction
▪ Compliance with all MBP policies
▪ Transparency regarding medicine costs and pricing, rebate arrangements and amounts, and any other fees that are charged to the PBM
▪ Provisions for auditing provider performance by the PBM
▪ Provision for auditing the PBM’s performance by the MBP, preferably on a rolling basis rather than one massive audit each year. Audits should consider financial compliance with contract terms, service quality, and responsiveness to client needs

REFERENCES
ANNEX 3. MBP SAMPLE MONITORING AND EVALUATION INDICATORS AND DATA SOURCES

**Indicators derived from the plan’s general information systems**

- Total monthly and annual MBP revenues versus expenses
- Monthly and annual expenditure for plan administration and beneficiary services, by department
- Number of beneficiaries served, and new enrollment, per month and annual total
- Patient and provider satisfaction, measured by number of complaints received and results of satisfaction surveys
- Monthly and annual costs for claims processing and adjudication
- Monthly and annual total costs and medicine expenditures per member
- Monthly and annual total cost of medicines procured for in-house dispensing
- Monthly and annual total cost of payments for prescriptions provided to outpatients
- Monthly and annual total cost of payments for inpatient medicines (if they are billed separately from other patient charges)
- Monthly and annual cost of payments for specialty medicines or health technologies
- Monthly and annual value of rebates or discounts from manufacturers
- Average turnover time for claims adjudication and payments
- Number of complaints received and processed, sorted by prescribers, dispensers, and beneficiaries

**Indicators derived from compiling and analyzing claims data or dispensing records**

- Numbers and average cost of prescription claims per month and annual, sorted by prescribers, pharmacy providers, and beneficiaries.
• Monthly and annual medicines cost per each beneficiary, and ABC-type analysis of “high use/high cost” member utilization
  ▪ Monthly and annual expenditure on medicines per each prescriber, and ABC-type analysis of high volume/high cost prescribers.
  ▪ Monthly and annual expenditures on medicines per pharmacy provider/dispenser and ABC-type analysis of high volume/high cost dispenser
  ▪ Monthly and annual use of specific medicines in specific therapeutic category, with analysis of use by individual prescribers, providers
  ▪ Generic prescribing/dispensing rate by prescriber and by dispenser; number of missed substitution opportunities by prescriber and dispenser
  ▪ Percentage of formulary adherent prescriptions and number of incidents of non-formulary prescriptions, sorted by prescribers and dispensers
  ▪ Exception requests and approval/rejection rates sorted by prescribers and dispensers and beneficiaries; incidents of potential fraud or abuse of medicines, sorted by prescriber, dispenser, and beneficiary
  ▪ Drug utilization problem reports by prescriber, dispenser, and beneficiary

Other relevant indicators for identifying potential fraud and abuse

• Excessive numbers of patient encounters reported for specific providers, suggesting potential lack of appropriate care, “prescription churning”, or falsified claims
• High number of referrals to specialists
• Evidence of having and using conflict of interest policies
• Consistently poor patient outcomes and hospitalization for beneficiaries treated by certain providers (may suggest lack of treatment or under-treatment)
• Reports or complaints from regulatory agencies, beneficiaries, or providers concerning potential fraud and abuse (including anonymous reports to “complaint hotlines”)

Information derived from special purpose studies

• Results of studies of patient adherence to prescription use instructions
• Results of satisfaction surveys, covering prescribers, dispensers, and beneficiaries
• Results of interventions to correct behavior of providers or beneficiaries
Corrupt practices by plan administrators

▪ Corruption involving staff or managers of the benefit program, whereby providers kick back payments in exchange for approval of fraudulent or abusive claims.

▪ Approval of exemptions from cost sharing or approval of other plan benefits for people or groups who are not really eligible for the benefit or exemption. This may involve financial corruption (selling exemptions or benefits) or simply bowing to family, clan, or other pressures (including political pressure).

Provider fraud

▪ Billing for medicines, equipment and services not actually received by an eligible beneficiary

▪ Billing using the provider ID of another provider

▪ Falsifying a diagnosis or medical record to justify use of medicines or procedures that are not really needed

▪ Billing for medicines separately when the provider contract calls for bundled billing

▪ Splitting claims into multiple submissions to avoid detection of improper billing

▪ Medicine shorting - billing for more medicines or greater quantities than are actually dispensed

▪ Prescription splitting – dispensing less than the prescribed quantity, and telling the patient to return for a second visit, thereby billing for two dispensing fees for the same prescription

▪ Billing for brand name medicines when a generic was actually dispensed

▪ Upcoding—billing for a more costly service than the one actually provided

▪ Duplicate billing—billing more than once for a service or medicine provided
▪ Exempting beneficiaries from cost sharing when they are not eligible for exemption
▪ Falsification of medical or dispensing records to justify payment
▪ Billing for services or medicines provided to ineligible beneficiaries or non-existent people (including dead people)
▪ Receiving payments or kickbacks to induce prescribers or beneficiaries to switch a prescription to a medicine supplied by the firm providing the kickback
▪ Engaging in fraudulent arrangements with beneficiaries, buying back all or part of a dispensed prescription and reselling it while billing the MBP for the full prescription

**Beneficiary fraud**

▪ Identity theft, obtaining services under the name of another beneficiary
▪ Falsification of eligibility for plan membership
▪ Misrepresentation on application for coverage
▪ Filing false claims, when the plan reimburses the beneficiary for covered services
▪ Forging prescriptions
▪ Obtaining prescriptions for resale to other beneficiaries or resale to a service provider
▪ Obtaining prescriptions for use by family members or associates
▪ Doctor shopping or dispenser shopping to obtain medicines and services that are not medically necessary (may involve narcotics abuse or attempts to receive treatment that is more expensive than required)
▪ Visits to multiple prescribers to obtain treatment for the same health problem, often coupled with schemes to resell some or all of the medicines received
▪ Falsely reporting loss of medicines or covered equipment to obtain replacements which are often used for resale (or personally abused as can be the case with narcotics)

**Abuse of the benefit**

Examples of abuse of the medicines benefit include—

▪ Overutilization of medicines and prescribing and dispensing medicines which are not medically necessary
▪ Excessive numbers of prescriptions per patient or excessive quantities prescribed and dispensed
▪ Unnecessary prescribing or dispensing of medicines that are not on the formulary or consistent with STG even coupled with requesting exception approval for non-covered medicines and services when it is not really medically necessary
▪ Prescribing and dispensing of expensive medicines when more cost-effective alternatives are available
▪ Prescribing or dispensing of brand name products rather than generic products when there is no medical justification
▪ Prescribing or dispensing refills when they are not necessary
▪ Charging unjustifiably high fees for services not explicitly covered in the provider contract
▪ Beneficiary doctor shopping to obtain prescriptions when the first prescriber suggests no medicine is needed
▪ Beneficiaries who see multiple providers and obtain multiple courses of treatment for the same health problem

### ANNEX 5. MODELS OF MANAGED ENTRY AGREEMENT IN THE EUROPEAN UNION

<table>
<thead>
<tr>
<th>MODEL NAME AND DESCRIPTION</th>
<th>FEATURES</th>
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<tbody>
<tr>
<td><strong>Belgium</strong></td>
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</table>
| **Budget capping**         | ▪ Budget cap  
▪ May be linked to data collection as part of an observational study or risk-sharing |
| **Compensation mechanism** | ▪ Compensation mechanism  
▪ Data collection |
| Price-volume agreement     |          |
| **Cyprus**                 |          |
| **Price-volume agreement upfront agreement**: Price reduction as the number of cases increases (within the same indication) | ▪ Registry |
| **Price-volume agreement upfront agreement**: Payments according to dose capping due to dosage scheme uncertainty or wastage uncertainty | ▪ Patient registry |
| **Price-volume agreement upfront agreement**: Discounts or free goods requested in case of uncertain and/or unfavorable efficacy or cost effectiveness data | ▪ Patient registry  
▪ Usually in line with National Institute for Health and Care Excellence (NICE) decisions  
▪ Patient access scheme if available |
| **Discounts for usage extension** | ▪ Registry |
| **Czech Republic**         |          |
| **Very innovative products (VILP) + AIFA notes**: Conditional reimbursement for 12 months for specific indications where the data on efficiency are to be collected | ▪ Limited reimbursement (specific patient subgroups, after failure of alternative treatment, limited number of doses)  
▪ Data collection |
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<thead>
<tr>
<th>MODEL NAME AND DESCRIPTION</th>
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<tbody>
<tr>
<td><strong>France</strong></td>
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<tr>
<td>Price/volume agreement:</td>
<td>For each drug, different levels of sales are and associated repayments are defined. Repayments are later converted into a price cut</td>
</tr>
<tr>
<td>Agreement on daily cost of treatment:</td>
<td>A target of daily cost of treatment is set. If it is exceeded, the company repays the excess</td>
</tr>
<tr>
<td>Study requirement:</td>
<td>The company is required to carry on a specific study concerning the real-life use of the drug. The price can be revised on the basis of its results</td>
</tr>
<tr>
<td>Risk-sharing agreement:</td>
<td>A price is set on higher basis than the existing evaluation of the product. If, after additional studies, the product gets a better evaluation, the price is maintained. If not, it is decreased and the company pays back the difference</td>
</tr>
<tr>
<td>• Uncertainty around effectiveness in real life</td>
<td></td>
</tr>
<tr>
<td><strong>Italy</strong></td>
<td></td>
</tr>
<tr>
<td>Risk sharing:</td>
<td>Discount on price of initial therapy cycle(s) for non-responder patients, identified following clinical evaluation in a pre-set time frame</td>
</tr>
<tr>
<td>• Discount for non-responders</td>
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<tr>
<td>• Conditional treatment continuation (only for patients who positively respond to the drug)</td>
<td></td>
</tr>
<tr>
<td>• Monitoring registry</td>
<td></td>
</tr>
<tr>
<td>Payment by results:</td>
<td>Initial cycle(s) fully reimbursed by manufacturer for non-responder patients (fully reimbursed by the National Health Service for responders), identified following clinical evaluation in a pre-set time frame</td>
</tr>
<tr>
<td>• Full reimbursement for non-responders</td>
<td></td>
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<tr>
<td>• Conditional treatment continuation (only for patients who positively respond to the drug)</td>
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<tr>
<td>• Monitoring registry</td>
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</tr>
<tr>
<td>Cost sharing:</td>
<td>Discount on price of initial therapy cycle(s) for all eligible patients</td>
</tr>
<tr>
<td>• Initial discount for all eligible patients</td>
<td></td>
</tr>
<tr>
<td>• Conditional treatment continuation (only for patients who positively respond to the drug)</td>
<td></td>
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<tr>
<td>• Monitoring registry</td>
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<tr>
<td>Monitoring registries:</td>
<td>Registries track the eligibility of patients and the complete flow of treatments, which guarantees appropriate use of medicines according to their approved indications</td>
</tr>
<tr>
<td>• Collection of patient-level data including information on eligibility for treatment, length of treatment, administered doses, epidemiological data, adverse drug reactions</td>
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<tr>
<td>Volume-based agreements:</td>
<td>The Italian Medicines Agency negotiates a volume of sales, related to a target population, with the manufacturer. The volume of sales, exceeding the pre-set threshold, will have to be paid back by the manufacturer to the National Health Service</td>
</tr>
<tr>
<td>• Monitoring databases providing sales and expenditures of pharmaceuticals</td>
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<tr>
<td>MODEL NAME AND DESCRIPTION</td>
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<tr>
<td><strong>AIFA-Notes</strong>: reimbursement is limited to specific patient sub-groups. The AIFA Note is reported by the general practitioner on the prescription form, which will allow the patient to get the medicinal product free of charge</td>
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<tr>
<td><strong>Therapeutic plans</strong>: diagnosis and treatment must be reported exclusively by specialized health care centers identified at regional level. This tool guarantees the reimbursement of certain medicines for the authorized therapeutic indications only under close monitoring of the specialists</td>
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<tr>
<td><strong>Lithuania</strong></td>
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| **Price volume agreements** | ▪ The manufacturer has to return a part of the excess expenditure to the NHIF  
▪ Collection of information about medicines consumption and expenditure |
| **Pay back agreements** | ▪ Pay back mechanism is applied to pharmaceuticals, when reimbursed price is too high compared with similar pharmaceuticals  
▪ Collection of information about medicines consumption and expenditure |
| **Expenditure cap agreement** | ▪ Manufacturer returns excess expenditure to the NHIF  
▪ For drugs that are already on the market and whose expenditure is more than 1 million and 1% of all expenditure for drug reimbursement.  
▪ Collection of information about medicines consumption and expenditure |
<p>| <strong>Malta</strong> | |
| <strong>Dose capping</strong> | |
| <strong>The Netherlands</strong> | |
| <strong>Coverage with evidence development</strong>: Coverage is granted under the condition that cost-effectiveness is determined within a four-year period | ▪ Submission of a cost-utility analysis to support continued reimbursement after the initial 4-year study period |</p>
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<tr>
<td><strong>Portugal</strong></td>
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| **Price-volume agreement:**  The manufacturer is required to reimburse the NHS if expenditure has exceeded the agreed budget |   ▪ Definition of the universe of eligible patients  
▪ Establishment of an annual budget limit for NHS  
▪ Re-evaluation of therapeutic added-value and cost-effectiveness at the end of the first two-year period  
▪ If the re-evaluation is positive, the agreement is extended for another two years (for hospital medicines) and new budget limits are established, based on previous sales data, new maximum prices (if they changed), and forecasted evolution of the medicine and the market  
▪ Alternatively, the medicine is included in a global list of reimbursed medicines (without agreement); the manufacturer must submit quarterly data on sales (volume, expenditure, and prices) to Infarmed  
▪ Promotional activities are limited to the therapeutic indications approved for the medicine  
▪ Some agreements have an additional pay-back scheme to guarantee acceptable prices for NHS, while maintaining list prices; for these agreements, the manufacturer must reimburse the NHS the difference between the approved list price and the discounted price for NHS |
| **Coverage with evidence development:** reimbursement extension after the initial two-year period is conditional to the provision of additional data on cost-effectiveness |   ▪ Re-evaluation of therapeutic added-value and cost-effectiveness at the end of the first two-year period  
▪ If the re-evaluation is positive, the agreement is extended for another two years (for hospital medicines) and new budget limits are established, based on previous sales data, new maximum prices (if they changed), and forecasted evolution of the medicine and the market  
▪ Alternatively, the medicine is included in a global list of reimbursed medicines (without agreement); the manufacturer must submit quarterly data on sales (volume, expenditure, and prices) to Infarmed  
▪ Promotional activities are limited to the therapeutic indications approved for the medicine  
▪ Some agreements have an additional pay-back scheme, to guarantee acceptable prices for NHS, while maintaining list prices; for these agreements, the manufacturer must reimburse the NHS the difference between the approved list price and the discounted price for NHS |
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<td><strong>Sweden</strong></td>
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<tr>
<td><strong>Coverage with evidence development</strong></td>
<td>▪ Depending on the type of uncertainty the manufacturer is required to submit data on use and/or cost-effectiveness</td>
</tr>
<tr>
<td><strong>UK - England and Wales</strong></td>
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</tbody>
</table>
| **Patient access schemes**: proposed by a pharmaceutical company and agreed between the company and the Department of Health, with input from NICE, to facilitate patient access to cost-effective innovative medicines | ▪ Discount  
▪ Initial free doses  
▪ Dose capping |