

Criteria - Shoulder

| Criteria - A* Ratings | 3A* | 5A* | 7A* | 10A* |
|--|------|------|------|-------|
| Minimum number of centres outside development centre(s) | 3 | 3 | 3 | 3 |
| Minimum total cohort | 100 | 150 | 200 | 250 |
| Minimum at risk at benchmark time | 100 | 125 | 150 | 175 |
| Maximum revision rate ‡ | 5.0% | 7.0% | 9.0% | 12.0% |
| Mandatory linked PROMS score (any validated score on at least 50 patients) | | | | |

‡ The upper 95% confidence interval for KM revision rate (1 - Survival) must be lower than the specified level

| Criteria - A Ratings | 3A | 5A | 7A | 10A |
|--|------|------|------|-------|
| Minimum number of centres and surgeons | 3 | 3 | 3 | 3 |
| Minimum total cohort | 100 | 150 | 200 | 250 |
| Minimum at risk at benchmark time | 40 | 40 | 40 | 40 |
| Maximum revision rate ‡ | 5.0% | 7.0% | 9.0% | 12.0% |

Voluntary linked PROMS score (any validated score)

‡ The upper 95% confidence interval for KM revision rate (1 - Survival) must be lower than the specified level

| Criteria - B Ratings | 3B | 5B | 7B | 10B |
|---|------|------|------|-------|
| Minimum number of centres and surgeons | 1 | 1 | 1 | 1 |
| Minimum total cohort | 50 | 50 | 50 | 50 |
| Minimum at risk at benchmark time | 10 | 10 | 10 | 10 |
| Maximum value of 95% lower confidence limit for revision rate | 5.0% | 7.0% | 9.0% | 12.0% |

| Pre-Entry A* | Pre-Entry |
|--------------|-----------|
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Product launched under Beyond Compliance

Products details provided to ODEP

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