

## GUIDANCE STATEMENT

### Thuasne ActionReliever® off-loading knee brace for osteoarthritis

PAC recommendations	
<b>Indication</b>	Knee osteoarthritis
<b>Commissioning recommendation</b>	<p><b><u>Not recommended for prescribing in primary care.</u></b></p> <p>Routine use of Thuasne ActionReliever® off-loading knee brace is not recommended. It may have a limited place in therapy for some patients including those where surgery is contra-indicated. However, fitting and support from a trained orthotist or physiotherapist or other specialist healthcare professional is essential to ensure maximum benefit is achieved.</p> <p>If after specialist consultation, Thuasne ActionReliever® off-loading knee brace is considered to be the best option for the patient, it should be supplied by a Specialist or secondary care clinic as part of the activity costs.</p>

## Background

Osteoarthritis (OA) is defined as a disorder of synovial joints which occurs when damage triggers repair processes leading to structural changes within a joint. Joint damage may occur through repeated excessive loading and stress of a joint over time, or by injury.<sup>1</sup> The main symptoms of osteoarthritis are joint pain and stiffness, and problems moving the joint. Some people also have symptoms such as: swelling, tenderness, grating or a crackling sound when moving the affected joints. Any synovial joint can be involved, and the most commonly affected peripheral joints are the knees, hips, and the small joints of the hand.<sup>1,2</sup>

The knee has three compartments in which osteoarthritis (OA) can occur; medial (inside tibiofemoral) compartment, lateral (outside tibiofemoral) compartment and patellofemoral (kneecap) compartment. Damage ranges from mild to severe and can affect one or multiple compartments.<sup>3</sup>

Osteoarthritis is a long-term condition and cannot be cured, but it does not necessarily get any worse over time and it can sometimes gradually improve. Mild symptoms can sometimes be managed with simple measures including: regular exercise, losing weight if overweight, wearing suitable footwear, or using special devices, such as basic knee supports or heel insoles to reduce the strain on the joints during everyday activities. If symptoms are more severe, additional treatments such as painkillers and a structured exercise plan with a physiotherapist may be needed. In a small number of cases, where these treatments have not helped or the damage to the joints is particularly severe, surgery may be needed to repair, strengthen or replace a damaged joint.<sup>2</sup>

There are broadly four types of knee brace; functional, prophylactic, rehabilitative, and the unloader/offloading type. There is also a fifth type of support known as a knee sleeve, which is often referred to as a knee brace, but is technically different.<sup>4,5</sup> The type of knee brace required is determined by the type and extent of the knee injury/condition and the knee compartment or compartments affected.<sup>2-4</sup>

An unloader/offloading knee brace, also known as a valgus or distraction-rotation knee brace<sup>6,7</sup> exerts pressure on the thigh bone, thereby unloading the pressure from the affected area and forcing the knee to bend on the opposite side of the affected area. This reduces compression, inflammation, and resultant pain. They are generally unicompartmental and consequently can only unload force from one side of the knee either medial or lateral tibiofemoral compartments. A new tri-compartment unloader/offloading knee brace, the Levitation 2®, is also available which can reduce the force throughout the entire knee including the knee cap (patellofemoral), effectively acting as a shock absorber.<sup>3</sup>

An unloader knee brace can also be used while waiting for a knee replacement surgery as the brace helps to relieve stress from the injured knee before the surgery.<sup>5,6</sup>

The Thuasne ActionReliever® is an unloader/offloading type brace, which is invisible under most clothing types according to the product website. Patients need to be measured in order to ensure the correct size is specified and supplied, along with which knee, left or right leg, and also which knee joint compartment is affected; either medial or lateral compartment. The product website claims that it requires minimal additional fitting and that it can be routinely used in patients with either medial or lateral unicompartmental OA, or unicompartmental knee conditions requiring load reduction.<sup>5</sup> It is not indicated for patellofemoral OA or tricompartmental OA.

Several other different brands of unloader or offloading knee brace are available for purchase in the UK with prices varying from £40 to £600 per device, depending on the exact type and level of custom fit required.<sup>8</sup>

The Thuasne ActionReliever® was added to the Drug Tariff in November 2019 and is the only knee pressure offloading device (knee brace/orthotic device/appliance) available for prescribing in primary care. The current price is £195.00 per device.<sup>9</sup>

## Summary of evidence

Current NICE Guidance for osteoarthritis recommends that people with osteoarthritis who have biomechanical joint pain or instability should be considered for assessment for bracing/joint supports/ insoles as an adjunct to their core treatments. The NICE guidance does not make any specific recommendation regarding the type or brand of bracing/joint support/insoles which should be used.<sup>10</sup>

There appears to be little evidence to confirm the efficacy of the Thuasne ActionReliever® itself or to compare its effectiveness to other brands or types of knee brace or different devices such as orthotic insoles.

There are currently two studies which are being cited by the company in support of this device.<sup>11,12</sup>

In the first, a prospective, observational study, 63 patients; mean age 50.9 years, with end stage unicompartmental osteoarthritis and who attended a district general hospital in Wales between August 2007 and February 2009, were prescribed an unloader knee brace while they were on the waiting list for surgery.<sup>11</sup> Patients with tricompartmental or patellofemoral osteoarthritis were excluded from the study, as were those who had previously undergone joint replacement surgery. The study aimed to use eight years of follow up data, to determine the short term and long term cost effectiveness of the unloader knee brace compared with no treatment while on the waiting list and total knee replacement (TKR). The brand of unloader knee brace used in this study is not confirmed but its cost is cited as £454.

Patients were taught how to fit the brace at home and asked to complete an EQ-5D-3L questionnaire, both before the brace was fitted and then subsequently when either the patient ceased using the brace or at the end of the study period in 2015. The EQ-5D-3L asks the patient to indicate if they have no problems, some problems or extreme problems with the following: mobility, self-care, usual activities, pain/discomfort and anxiety/depression.<sup>13</sup> For all patients the mean EQ-5D utility values increased from 0.01 at baseline to 0.4 at follow up, with an overall QALY gain of 0.435. Similar increases were observed across the duration of wear subgroups, with the largest mean increase observed for patients with a duration of wear between seven and 12 months; EQ-5D difference=0.443. At 24 months, 16 patients

(25.4%) were still wearing the unloader knee brace and if the patient symptoms were still tolerable at this stage, the chance of undergoing subsequent surgery declined significantly. Patients wore the brace for an average of eight months; range one to 24 months, with 40.5% ceasing to wear the brace within the first six months. Surgical interventions were required for 38 patients, of whom 50% required a TKR, 37% had uni-compartmental or partial knee replacement (UKR) and 13% had high tibial osteotomy (HTO).

The study authors concluded that at a mean cost of £625 (cost of brace plus clinician contact time), wearing an unloader knee brace for the entire TKR mean waiting list duration of eight months offered a patient QALY gain of 0.07, which provided an incremental cost-effectiveness ratio (ICER) of £9,599. A waiting list of at least four months appeared to ensure that the unloader knee brace remained cost effective, however if the TKR was immediately available then the TKR became more cost-effective than the knee brace alternative.

This was a small study and the overall validity of the costings and the costing model used is unclear, as the source for the treatment costs is not cited accurately. In addition, the authors noted that 43% of patients in the study, had soft tissue issues as a result of the brace being fitted poorly and postulated that follow up appointments at one, three and six months may be needed. The published costing model only factored in one follow up appointment at three to six months and therefore changing the number of follow ups required and the associated additional costs will change the ICER, however no further analysis or an additional ICER, based on revised costings involving additional follow ups was provided.<sup>11</sup>

The second study is a prospective, randomized, parallel group study conducted in Germany between 12 December 2016 and 28 February 2017 with 32 patients who had medial or lateral femorotibial osteoarthritis, grade two or three according to the Kellgren Lawrence system.<sup>12</sup> The patients were randomized to either a control group; n=15, or to the treatment group using the Genu OA orthosis device; n=17. Whilst this brace is made by Thuasne it is not clear if this is the identical brace to the ActionReliever®, although it would appear to be similar. The main outcome was extension of pain free walking distance after using the orthosis for two months. Secondary outcome measures included changes in the Lequesne index; pain on loading and pain at rest measure using a numerical rating scale (NRS), change in use of analgesics, subjective and objective range of movement, and patient tolerability for the device.<sup>12</sup> The Lequesne index is similar to the EQ-5D. It is a ten question survey pertaining to pain or discomfort, maximum distance walked, activities of daily living and is scored on a zero to 24 scale. Lower scores indicate there is less functional impairment.<sup>14,15</sup>

At two months, the change in the pain-free walking distance was increased in the orthosis group compared with the control group; 1.29 vs 0.20 (Fisher exact test (F) = 20.23, numerator degrees of freedom (ndf) 1, denominator degrees of freedom (ddf) 29; p=0.0001). The average intensity of pain at the end of a maximum 30-minute walk was reduced in the orthosis group by 1.06 (±0.66) points on the numerical rating scale; vs 0.13 (±0.35) in the control group. The change in pain under loading was increased in the orthosis group compared with the control group (F=22.13, ndf 1, ddf 29, p=0.0001). The resting pain was reduced only in the orthosis group from 1.59 (±1.00) to 1.53 (±0.94) and did not change in the control group. There was no difference between the groups at the end of the two-month treatment period with respect to the average values of resting pain. The Lequesne index dropped in the control group by an average of 0.17 (±0.36) to 8.27 (±3.48), while in the orthosis group, it was reduced by 0.68 (±0.71) to 6.94 (±2.86) (F=10.08; ndf 1, ddf 29, p=0.0035). A reduction of 17.3% in the use of analgesics was observed in the orthosis group; the reduction in the control group was 3.1%. However, this difference was not statistically significant (F=3.40; ndf 1, ddf 22, p=0.0785). Patients in the orthosis group reported that the orthosis was unpleasant and that the pressure of the corrective straps was annoying and uncomfortable.<sup>12</sup>

No patients appear to have been lost to follow up, but this was another small study, which has to date, only been published in the trade journal of the Federal Association of Orthopaedic Technology, which represents the interests of all stakeholders in the orthopaedic technology market across Germany, Austria and Switzerland. As such it has not been subjected to independent peer review and not indexed

in the usual medical literature databases such as Medline or Embase. The results should be interpreted with caution.

No further studies potentially in relation to the Thuasne ActionReliever® off-loading knee brace have been identified.

Several studies have been published which consider the effectiveness of offloading or unloading knee type braces in general. Most studies involved small numbers of patients and were often uncontrolled with a high risk of bias producing conflicting results in relation to possible improvements in pain, quality of life and disease progression. The effect, if any of unloading or valgus knee braces, on the time to total knee replacement or other corrective surgery is uncertain.

A Cochrane review published in 2015, aimed to assess the benefits and harms of knee braces and foot/ankle orthoses in the treatment of patients with OA of the knee.<sup>7</sup> Thirteen studies, involving 1,356 participants, were included which reported results where study participants with early to severe knee OA (Kellgren & Lawrence grade I-IV), were treated with a knee brace (valgus knee brace, neutral brace or neoprene sleeve) or an orthosis (laterally or medially wedged insole, neutral insole, variable or constant stiffness shoe) or were given no treatment. Several of the included studies had a high risk of selection bias, detection bias, reporting bias or performance bias and were considered to be low quality evidence.

Four of the included studies compared brace versus no treatment, but only one provided useful data for meta-analysis at 12-month follow-up. This one study (n=117, low quality evidence) showed lack of evidence of an effect on visual analogue scale (VAS) pain scores (absolute percent change 0%, mean difference (MD) 0.0; 95% confidence interval (95% CI)-0.84 to 0.84), function scores (absolute percent change 1%, MD 1.0, 95% CI-2.98 to 4.98) and health-related quality of life scores (absolute percent change 4%, MD-0.04; 95% CI-0.12 to 0.04) after 12 months. Many participants stopped their initial treatment because of lack of effect (24 of 60 participants in the brace group and 14 of 57 participants in the no treatment group; absolute percent change 15%, risk ratio (RR) 1.63, 95% CI 0.94 to 2.82). The other studies reported some improvement in pain, function and health-related quality of life (P value  $\leq 0.001$ ). Stiffness and treatment failure (need for surgery) were not reported in the included studies. Data for the comparison of laterally wedged insole versus valgus knee brace could not be pooled.<sup>7</sup>

The review authors concluded that the low quality evidence available was inconclusive for the benefits of bracing for pain, stiffness, function and quality of life in the treatment of patients with medial compartment knee OA and showed lack of effect in improvement between patients treated with a valgus knee brace and those treated with a laterally wedged insole. The optimal choice for an orthosis remains unclear, and long-term implications are lacking.<sup>7</sup>

The use of braces for OA is not clear from international medical guidelines. The current (2019) OsteoArthritis Research Society International (OARSI) guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis state that bracing of the knee (described as a biomechanical intervention in the previous guidelines) are not recommended due to inadequate efficacy and safety balance, stemming from very poor quality evidence.<sup>16</sup>

The 2019 American College of Rheumatology and the Arthritis Foundation evidence based guideline for the management of hand, hip and knee OA states that tibiofemoral knee braces are strongly recommended for patients with knee OA in whom disease in one or both knees is causing a sufficiently large impact on ambulation, joint stability, or pain to warrant use of an assistive device, and who are able to tolerate the associated inconvenience and burden associated with bracing. Patellofemoral braces are conditionally recommended for patients with patellofemoral knee OA in whom disease in one or both knees is causing a sufficiently large impact on ambulation, joint stability, or pain to warrant use of an assistive device. The recommendation is conditional due to the variability in results across published trials and the difficulty some patients will have in tolerating the inconvenience and burden of these braces. Optimal management with knee bracing is likely to require that clinicians are familiar with the various types of braces and where they are available and have expertise in fitting the braces. Patient Voting Panel members strongly emphasized the importance of coordination of care between primary care providers, specialists, and providers of braces.<sup>17</sup>

## Financial considerations

The Thuasne ActionReliever® was added to the Drug Tariff in November 2019 and is the only knee pressure offloading device (knee brace/orthotic device/appliance) available for prescribing in primary care. The Drug Tariff price is currently £195.00 per device.<sup>9</sup> The knee brace has a six month warranty and the company expects each knee brace to last between two and five years.<sup>18</sup> Several alternative brands and knee braces are available in the UK to purchase from sites such as Amazon UK, with indicative prices ranging between £50 and £600 per device.<sup>8</sup> Sizing, fit and design of knee brace are often key parameters to the overall effectiveness, and patients should consult with an appropriate specialist to ensure they receive the most effective treatment options.<sup>6,8</sup>

The current cost of a knee surgery, including total knee replacement currently ranges from £2,554 to £9,095 excluding outpatient attendance costs and follow up. Prices for community physiotherapy and orthotic services are negotiated locally and not subject to national PbR tariff pricing.<sup>19</sup>

Osteoarthritis is the most common joint disease worldwide, affecting an estimated 10% of men and 18% of women over 60 years of age. It is estimated that 8.75 million people aged over 45 years in the UK have sought treatment for osteoarthritis.<sup>1</sup> A population-based study of primary care data in England between 2000 and 2010 (total practice population of 94,955) found newly diagnosed cases of osteoarthritis occur in nine per 1000 at-risk adults each year. The risk of developing osteoarthritis increases with age with almost a third of women and a quarter of men between 45 and 64 years of age having sought treatment for osteoarthritis. This rises to almost half of people aged 75 years and over. The prevalence is higher in women than in men and varies with the affected joint.<sup>1</sup>

The total number of patients who would require an offloading knee brace is uncertain.

## Place in Therapy

The current level of evidence is insufficient and further data is required to confirm the place in therapy of the Thuasne ActionReliever® off-loading knee brace.

Routine use of Thuasne ActionReliever® off-loading knee brace is not recommended. It may have a limited place in therapy for some patients including those where surgery is contra-indicated. However, fitting and support from a trained orthotist or physiotherapist or other specialist healthcare professional is essential to ensure maximum benefit is achieved and the patient would also need to have the agility and necessary dexterity to put on and take off the brace correctly. It is not suitable for all osteoarthritis patients, and opinion from East of England orthopaedic specialists indicates that it is unlikely to be of benefit for patients whilst waiting for knee surgery.

At present, where knee braces are required or recommended by local specialists, these are usually supplied as part of secondary care services, which allows patients to be properly assessed. This also allows the most appropriate and effective type of brace to be supplied for the type and severity of osteoarthritis being experienced by the patient.

## Comments sought from

East of England clinicians via PAC members.

Author: Victoria Gibson on behalf of PAC

## Document history

PAC approval date	17th May 2021
Version	v1
Consultation process	East of England Health professionals including orthopaedic specialists, specialist Physiotherapists and Orthotists. PAC members
QA process	Katie Smith, Director of Clinical Quality, PrescQIPP. 8th June 2021

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## Appendix 1: Assessment against Ethical and Commissioning Principles

### 1. Treatment assessed

Thuasne ActionReliever® Off-loading Knee Brace for Osteoarthritis.

### 2. East of England Priorities Advisory Committee Recommendation

Not recommended for prescribing in primary care.

Routine use of Thuasne ActionReliever® off-loading knee brace is not recommended. It may have a limited place in therapy for some patients including those where surgery is contra-indicated. However, fitting and support from a trained orthotist or physiotherapist or other specialist healthcare professional is essential to ensure maximum benefit is achieved.

If after specialist consultation, Thuasne ActionReliever® off-loading knee brace is considered to be the best option for the patient, it should be supplied by the Specialist or secondary care service as part of the activity costs.

### 3. Clinical Effectiveness

The current level of evidence is insufficient and further data is required to confirm the place in therapy of the Thuasne ActionReliever® off-loading knee brace.

### 4. Cost Effectiveness

There is limited data available. The cost effectiveness of Thuasne ActionReliever® off-loading knee brace has not been established.

### 5. Equity

No issues identified.

### 6. Needs of the community

The number of patients who may require a specialist knee brace is unknown, but could represent a large number of patients. It is estimated that 8.75 million people aged over 45 years in the UK have sought treatment for osteoarthritis.

Osteoarthritis is a long-term condition and cannot be cured, but it does not necessarily get any worse over time and it can sometimes gradually improve. Mild symptoms can sometimes be managed with simple measures including: regular exercise, losing weight if overweight, wearing suitable footwear, or using special devices, such as basic knee supports or heel insoles to reduce the strain on the joints during everyday activities. If symptoms are more severe, additional treatments such as painkillers and a structured exercise plan with a physiotherapist may be needed and in severe cases, knee surgery or knee joint replacement may be warranted.

### 7. Need for healthcare (incorporates patient choice and exceptional need)

There may be a small number of osteoarthritis patients, particularly those where surgery is contra-indicated who may benefit from a specialist knee brace. For these patients, the most appropriate knee brace should be selected and fitted by a trained specialist to ensure the patient achieves the maximum benefit.

### 8. Policy drivers

None.

### 9. Disinvestment

None.