### Prior Authorization Review Panel
#### MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

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<th>Plan: Aetna Better Health</th>
<th>Submission Date: 11/01/2018</th>
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<tr>
<td>Policy Number: 0639</td>
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**Type of Submission – Check all that apply:**
- ☒ New Policy*
- ☐ Revised Policy
- ☐ Annual Review – No Revisions

*All revisions to the policy must be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below:

**CPB 0639 Autotransfusers**

Policy is new to Aetna Better Health of Pennsylvania.

**Name of Authorized Individual (Please type or print):**

Dr. Bernard Lewin, M.D.

**Signature of Authorized Individual:**

[Signature]
Aetna considers the following autotransfusion and cell saver devices medically necessary for procedures that may deplete blood volume:

1. Emergency or intra-operative autotransfusion, where blood is collected from the wound or a body cavity, processed, and then returned to the individual.

2. Hemodilution or cell washing autotransfusion, where blood is collected and simultaneously replaced with sufficient volume of crystalloid or colloid solution.

3. Post-operative autotransfusion (usually done within 2 hours with a chest tube collection device), where the blood from the chest (or other sterile operative sites) is re-infused following heart surgery and traumatic hemithorax.

Aetna considers autotransfusion and cell saver devices experimental and investigational for all other indications because their effectiveness for indications other than the ones listed above has not been established.

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.*
**Note:** Autotransfusion and cell saver devices are not considered medically necessary for members undergoing procedures that are expected to require less than 2 units of blood.

Examples of procedures that may involve major blood loss and may require autologous blood transfusions or the use of autotransfusers include, but are not limited to:

1. Cardiopulmonary bypass surgery and other high-risk cardiac surgeries (e.g., abdominal aortic surgery)
2. Ectopic pregnancy
3. Emergency hemorrhage
4. Hysterectomy
5. Organ transplantation
6. Orthopedic surgery (e.g., hip arthroplasty)
7. Post-operative hemorrhage
8. Vascular femoral grafts.

**Background**

An autotransfuser is a mechanical device that is used in the process of collecting and re-infusing blood lost from hemorrhage. Different forms of autologous transfusers include intra-operative, emergency, or post-operative salvage devices and hemodilution devices used to re-infuse a patient's own blood.

Many people have safety concerns about receiving transfusions of donated blood. "Cell salvage" with autotransfusion is a technique designed to reduce the need for such transfusions. The technique involves collecting blood from surgical sites, to be transfused back into the person during or after surgery if necessary. The blood is either "washed" before transfusion or transfused directly after being filtered (unwashed). Risks from cell salvage include infection and blood clotting problems.
Autologous blood transfusion or the use of autotransfusers are contraindicated in blood exposed to bacteria (an infected wound or blood with fecal contamination) or in blood with malignant cells.

A meta-analysis of studies of cell savers in cardiac and orthopedic surgery (Huet et al, 1999) found that both devices that wash and do not wash salvaged blood decrease the proportion of patients who receive a peri-operative allogeneic transfusion. These investigators found, however, that the post-operative use of devices that do not wash salvaged blood in cardiac surgery was only marginally effective. The authors noted that cell salvage did not appear to increase adverse events, although side-effects were inconsistently reported and the number of patients studied was relatively small.

A Cochrane evidence review (Carless et al, 2003) found evidence suggesting that cell salvage reduces the need for transfusions of donated blood. However, the investigators concluded that better quality research is needed to assess the cost-effectiveness of cell salvage across a range of surgical settings compared to other blood-sparing techniques.

Reitman et al (2004) evaluated the necessity and cost-effectiveness of the use of Cell Saver for adult lumbar spine fusions. These investigators concluded that while patients in the Cell Saver group did require fewer post-operative transfusions, the difference was not as much as expected. In elective fusions for degenerative conditions of the lumbar spine, blood requirements can usually be satisfied with pre-donation of autologous blood. With contemporary practices of pre-donation, the use of the Cell Saver appears to be neither necessary nor cost-effective during most elective lumbar fusions.

Gause et al (2008) examined the effectiveness of using intra-operative Cell Saver in decreasing the need for blood transfusion. Data were collected from 188 patients undergoing
consecutive instrumented lumbar laminectomy and fusion. A total of 141 of these patients had Cell Saver used during their procedures, whereas 47 did not. In addition, previously published data from similarly treated patients were used for analysis. Operative blood loss, autologous and allogeneic blood transfusions, discharge hematocrit, and patient factors were analyzed. A significant increase in the number of blood transfusions was found in the Cell Saver group, which also had a significantly increased blood loss compared with the non-Cell Saver group. Using analysis of co-variance, these investigators determined the effect of blood loss on the need for transfusion. The results showed that correcting for blood loss eliminated the significance in the transfusion difference, but Cell Saver still was not able to decrease the transfusion need. Comparing their current results with their previously published results also demonstrated no benefit of Cell Saver use. The authors concluded that the use of Cell Saver in instrumented lumbar fusion cases was not able to decrease the need for blood transfusion. Furthermore, Cell Saver use was associated with a significantly higher blood loss.

In a retrospective review, Scannell et al (2009) examined if Cell Saver use in patients with acetabular fractures reduces the volume or rate of allogeneic blood transfused intra-operatively and post-operatively and if this translated to a decrease in blood-related charges to the patient. A total of 186 patients with operatively treated acetabular fractures were included in this study. All patients underwent open reduction internal fixation of their acetabular fracture. The decision to use Cell Saver was at the surgeon’s discretion. The volume and rate of intra-operative and post-operative allogeneic blood transfused and blood-related charges were evaluated. Cell Saver was used in 60 cases (32 %), and the average volume of blood autotransfused was 345 ml. No differences were observed in the rates (58.3 % versus 48 %, p = 0.1883) or the mean volumes (770 versus 518 ml, p = 0.0537) of intra-operative and post-operative allogeneic blood transfusions between the Cell Saver and the non-Cell Saver groups. Total
blood-related charges in the Cell Saver group were significantly higher than that in the non-Cell Saver group ($1,958 versus $694, p < 0.0001). Sub-analyses based on fracture pattern, injury severity score, body mass index, days to surgery, and estimated blood loss were performed. In each sub-analysis, no differences were observed in intra-operative and post-operative transfusion rates and volumes, and total blood-related charges were higher in the Cell Saver groups. The authors concluded that in the routine use of Cell Saver in acetabular surgery, there was no reduction in the volume or rate of allogeneic blood transfused intra-operatively or post-operatively. However, blood-related charges were significantly increased.

In a systematic review and meta-analysis of published randomized controlled trials, Wang et al (2009) examined the overall safety and effectiveness of cell salvage in cardiac surgery. Medline, Cochrane Library, Embase, and abstract databases were searched up to November 2008. All randomized trials comparing Cell Saver use and no Cell Saver use in cardiac surgery and reporting at least 1 pre-defined clinical outcome were included. The random effects model was used to calculate the odds ratios (OR, 95 % confidence intervals [CI]) and the weighted mean differences (WMD, 95 % CI) for dichotomous and continuous variables, respectively. A total of 31 randomized trials involving 2,282 patients were included in the meta-analysis. During cardiac surgery, the use of an intra-operative Cell Saver reduced the rate of exposure to any allogeneic blood product (OR 0.63, 95 % CI: 0.43 to 0.94, p = 0.02) and red blood cells (OR 0.60, 95 % CI: 0.39 to 0.92, p = 0.02) and decreased the mean volume of total allogeneic blood products transfused per patient (WMD -256 ml, 95 % CI: -416 to -95 ml, p = 0.002). There was no difference in hospital mortality (OR 0.65, 95 % CI: 0.25 to 1.68, p = 0.37), post-operative stroke or transient ischemia attack (OR 0.59, 95 % CI: 0.20 to 1.76, p = 0.34), atrial fibrillation (OR 0.92, 95 % CI: 0.69 to 1.23, p = 0.56), renal dysfunction (OR 0.86, 95 % CI: 0.41 to 1.80, p = 0.70),
infection (OR 1.25, 95 % CI: 0.75 to 2.10, p = 0.39), patients requiring fresh frozen plasma (OR 1.16, 95 % CI: 0.82 to 1.66, p = 0.40), and patients requiring platelet transfusions (OR 0.90, 95 % CI: 0.63 to 1.28, p = 0.55) between Cell Saver and non-Cell Saver groups. The authors concluded that current evidence suggests that the use of a cell saver reduces exposure to allogeneic blood products or red blood cell transfusion for patients undergoing cardiac surgery. Sub-analyses suggest that a Cell Saver may be beneficial only when it is used for shed blood and/or residual blood or during the entire operative period. Processing cardiotomy suction blood with a Cell Saver only during cardiopulmonary bypass has no significant effect on blood conservation and increases fresh frozen plasma transfusion.

Savvidou et al (2009) examined the use of cell saver blood autotransfusion in spinal surgery and evaluated the effectiveness and cost-effectiveness of cell saver blood autotransfusion during lumbar spine fusion in adults. A total of 50 consecutive candidates for postero-lateral fusion with internal fixation were prospectively randomized into either receiving peri-operatively cell saving autotransfusion (group A: 25 patients) or not (group B: 25 patients). The use of cell saving technique did not exclude the use of allogenic blood transfusion. Surgical indications were spinal stenosis, spondylolisthesis, adolescent idiopathic scoliosis, degenerative scoliosis and fractures. Medical and financial data were recorded. A cost-analysis was performed. Patients in group A received 880 +/- 216 ml from cell saver and 175 +/- 202 ml allogenic blood. The patients in group B received 908 +/- 244 ml allogenic blood. Blood volumes data collected were expressed in mean +/- SD values. The cost of blood transfusion in group A was 995 +/- 447 Euro per patient and 1,220 +/- 269 in group B (p < 0.05). The authors concluded that in elective lumbar fusion blood requirements can be satisfied with the use of autotransfusion. The use of cell saver appears to be useful and cost-effective during most elective lumbar fusions.
Bowen et al (2010) examined the effectiveness of intra-operative cell salvage systems in pediatric idiopathic scoliosis patients undergoing posterior spinal fusion with segmental spinal instrumentation. A total of 54 consecutive patients were studied: 21 non-cell saver and 33 cell saver patients. Data included age, body mass index, Cobb angle, peri-operative hemoglobin levels, mean arterial pressure, surgical time, levels fused, peri-operative estimated blood loss, and peri-operative transfusions. A Chi square and t- tests were performed for intra-operative and peri-operative allogeneic transfusion between groups. A regression analysis was performed between selected co-variates and allogeneic transfusion. Relative risk analysis examined significant co-variates regarding allogeneic transfusion rate. Allogeneic transfusion rates were lower in the cell saver group (6 % versus 55 % intra-operative and 18 % versus 55 % peri-operative, p < 0.05). Mean allogeneic transfusion volumes (ml/kg) were also lower (0.4 versus 9.1 intra-operative and 1.9 versus 11.1 peri-operative, p < 0.05). Multi-variate analysis confirmed these differences were independent of peri-operative blood loss, and also demonstrated that surgical time and blood loss were significantly related to allogeneic transfusion volume. The allogeneic transfusion relative risk was 2.04 in patients with surgery greater than 6 hours and 5.87 in patients not receiving cell saver blood. All patients with surgeries greater than 6 hours and estimated blood loss greater than 30 % of total blood volume received cell saver system blood. The authors concluded that cell saver use decreased allogeneic transfusion, particularly in surgeries greater than 6 hours with estimated blood loss greater than 30 % of total blood volume. This study confirmed the utility of routine cell saver use during posterior spinal fusion with segmental spinal instrumentation for idiopathic scoliosis.

Anderson and Panizza (2010) noted that endoscopic transnasal approaches to the skull base and intra-cranial disease are an emerging subspecialty. The limits of this approach are often dictated by exposure and blood loss. Cell
salvage techniques are widely used in other surgical fields. However, in otolaryngology, questions remain regarding its safety because work is performed in a contaminated field. These researchers presented the evidence for peri-operative cell saver blood transfusion in potentially contaminated fields and the need for further investigation of its use in endonasal surgery. Medline and evidence-based medicine reviews databases were searched for relevant articles. All English articles discussing autologous blood transfusion in endonasal surgery were reviewed. Despite a wide search pattern, no articles that discuss this topic were found in the English literature. Therefore, these investigators went on to present data on the general use of cell saver blood in contaminated fields. The authors concluded that cell saver blood is widely accepted in surgery. It offers many advantages in elective operations in which blood loss is expected to be significant. Cell saver blood has been transfused from contaminated fields in other forms of surgery without an associated increase in morbidity. There is good evidence that antibiotic prophylaxis is mandatory in this setting. There is no direct evidence that cell salvage blood is safe in endonasal surgery.

Reyes and colleagues (2011) examined if the use of cell saver (CS) systems reduce the need of blood products in low-risk patients undergoing cardiac surgery. Between February and June 2009, all low-risk patients (EuroSCORE less than 10 %) undergoing coronary or valve procedure were selected (n = 63). Exclusion criteria were: combined procedure, aorta procedure, redo surgery, emergency procedures, creatinine levels greater than 2 mg/ml, anemic patients and patients with a body surface area (BSA) less than 1.6 m2. Patients were randomized to undergo cardiac surgery with a CS system (group CS; n = 34) or without (control group [CO]; n = 29). All patients received tranexamic acid during the procedure. Need of blood products and clinical outcomes were analyzed in both groups. Mean age was 64.7+/-12.3 years old with 33 % of female patients. Baseline clinical characteristics and pre-operative blood count cell were similar in both groups. Mean
CS blood re-infused was 461 +/- 174 ml (maximum: 985; minimum: 259). A total of 59 red blood packages were transfused in 25 patients (mean of 1.02 +/- 1.3; range of 0 to 5). The proportion of patients being transfused was similar in both groups (CS: 40 % versus CO: 46.4 %; p = 0.79). Eleven plasma packages were transfused (CS: 8 versus CO: 3; p = 0.77) and 3 platelet pools were used in group CS and none in group CO (p = 0.08). Multi-variate analysis showed that pre-operative hemoglobin levels greater than 13.3 g/dL (relative risk [RR]: 0.29; CI: 0.09 to 0.99) and BSA greater than 1.74 (RR: 0.19; CI: 0.54 to 0.68) were protective against blood transfusion. The authors concluded that in low-risk patients CS system did not reduce the need of blood transfusion. Clinical outcomes were similar regardless of the use of a CS system. A low pre-operative hemoglobin level and a low BSA were related with the use of blood products.

The Society of Thoracic Surgeons and the Society of Cardiovascular Anesthesiologists’ updated clinical practice guideline on "Blood Conservation" (Ferraris et al, 2011) noted that during cardiopulmonary bypass, intra-operative autotransfusion, either with blood directly from cardiotomy suction or recycled using centrifugation to concentrate red cells, may be considered as part of a blood conservation program.

Shantikumar et al (2011) noted that abdominal aortic aneurysm (AAA) repairs, both elective and rupture, are associated with significant blood loss often requiring transfusion. Cell-salvage autotransfusion has been developed to reduce the need for allogeneic blood. These investigators reviewed the literature to delineate the role of cell salvage in reducing allogeneic blood use in open AAA repairs. A systematic search of the English-language literature was performed using the PubMed, Embase and Cochrane databases up to August 2010. A total of 23 studies were identified. While some data are conflicting, cell salvage appears to reduce overall use and exposure to allogeneic
blood, and reduces length of intensive care unit and hospital stay after elective AAA repairs. There may be additional benefit by combining cell salvage with other blood-conservation techniques. Use of cell salvage in ruptured AAA repairs consistently reduced blood-product requirements. The authors concluded that cell salvage appears to reduce blood-product use in both elective and rupture AAA repairs. Moreover, they stated that owing to the heterogeneity in methodology of published data, further study may be needed before cell salvage becomes standard practice in open AAA repairs.

Tavare and Parvizi (2011) examined if the use of intraoperative cell-salvage (ICS) leads to negative outcomes in patients undergoing elective abdominal aortic surgery. Altogether 305 papers were found using the reported search, of which 10 were judged to represent the best evidence to answer the clinical question. The authors, journal, date and country of publication, patient group studied, study type, relevant outcomes and results of these papers were tabulated. None of the 10 papers included in the analysis demonstrated that ICS use led to significantly higher incidence of cardiac or septic post-operative complications. Similarly, length of intensive treatment unit (ITU) or hospital stay and mortality in elective abdominal aortic surgery were not adversely affected. Indeed 2 trials actually show a significantly shorter hospital stay after ICS use, one a shorter ITU stay and another suggests lower rates of chest sepsis. Based on these papers, the authors concluded that the use of ICS does not cause increased morbidity or mortality when compared to standard practice of transfusion of allogenic blood, and may actually improve some clinical outcomes. As abdominal aortic surgery inevitably causes significant intra-operative blood loss, in the range of 661 to 3,755 ml as described in the papers detailed in this review, ICS is a useful and safe strategy to minimize use of allogenic blood.
Prieto et al (2013) stated that the role of a cell-saver device in the inflammatory response to cardiac surgery has not been well-documented. These investigators hypothesized that the use of a cell saver may reduce pro-inflammatory cytokine concentrations in patients undergoing cardiac surgery. A total of 57 patients presenting for first-time non-emergency cardiac surgery were prospectively randomized to control or cell salvage groups. Blood samples for inflammatory marker assays were collected from the arterial line on induction of anesthesia, at the end of cardiopulmonary bypass, 1 hour after surgery, and 24 hours after surgery. Plasma pro-inflammatory cytokines were analyzed using a sandwich solid-phase enzyme-linked immunosorbent assay. The highest cytokine levels were observed 1 hour after surgery. When comparing serum interleukin levels in both patient groups during the different peri-operative periods, these researchers found a higher interleukin-8 concentration 24 hours after the procedure, and higher concentrations of the p40 subunit of interleukin-12 at 1 hour and 24 hours post-operatively. The concentrations of interleukin-6 and p40 were greater in blood stored by the cardiotomy suction system than in blood processed by the cell saver (p = 0.01 in both cases). The interleukin-8 concentration was higher in the blood processed by the cell saver (p = 0.03). No significant differences were observed in interleukin-1 and interferon gamma levels in blood from both systems. Clinical outcomes were similar in both groups. The authors concluded that these findings suggested that cell salvage in low-risk patients undergoing their first elective cardiac procedure does not decrease the inflammatory response after surgery.

Mizuno et al (2011) noted that intra-operative, salvaged, autologous blood transfusions carried out with autotransfusion devices are commonly used for cardiovascular surgery, and also enable the treatment of massive hemorrhage in orthopedic and gynecologic surgeries to prevent potential complications of homologous blood transfusions, such as transmission of infection, immune reactions, and blood type
incompatibility. Transfusion of salvaged blood in oncologic surgery may cause hematogenous metastasis and dissemination of malignant tumor cells. However, some investigators have reported that blood irradiation or filtration using leukocyte reduction filters can prevent contamination by malignant tumor cells. The authors concluded that intra-operative autotransfusion with the combination of blood irradiation and leukocyte reduction filters could be therefore a promising technique for the treatment of profuse hemorrhage in oncologic surgery.

In a meta-analysis, Waters et al (2012) examined the risk of intraoperative blood salvage (IBS) during cancer surgery. A literature search was performed including the search phrases "blood salvage", "intraoperative blood salvage", "cell salvage", "cell saver", "cell saving", "autotransfusion" and "autologous transfusion". Data extracted from suitable papers included the authors' names, publication year, cancer type, exclusion criteria, sample size, length of follow-up, and the mean patient age. The primary end-point of this meta-analysis was a comparison of the OR for cancer recurrence or the development of metastases. A total of 11 studies were included in the analysis. The pooled summary of the OR was 0.65 (95 % CI: 0.43 to 0.98; p = 0.0391) using a random-effects model. Measures of heterogeneity, Q-statistics (p = 0.1615) and I(2) (30.90 %), did not indicate a high degree of between-study variability. The authors concluded that while significant variability existed between studies, the findings of this meta-analysis suggested that outcomes after the use of IBS are not inferior to traditional intraoperative allogeneic transfusion. Moreover, they stated that an adequately powered prospective, randomized trial of IBS use is needed to ascertain its true risk during cancer surgery.

Gakhar et al (2013) noted that there is no scientific literature regarding the role of cell salvage and autologous transfusion in metastatic spinal cancer. In a pilot study, these investigators examined the role of cell salvage during metastatic spine
surgery. A total of 16 spinal metastases patients who received red cell salvage using a leucocyte depletion filter (LDF) were enrolled in this study. Of these, 10 patients who received salvaged blood transfusion were included in the final analysis. Data collection involved looking at the case notes, operating room records and the prospectively updated metastatic spinal cancer database maintained in the spinal department. Cell salvage data was recovered from the central cell salvage database maintained in the anesthetic department. Amount of salvaged blood ranged from 120 to 600 ml (average of 318 ml). The average drop in hemoglobin was 1.65 units (range of 0.4 to 2.7 units). Three patients (30%) required post-operative allogeneic blood transfusion. The average follow-up was 9.5 months. One patient developed new lung metastasis at 7 months. No patient developed new liver metastases. Pre-operatively, 6 patients had diffused skeletal metastases. Of this subgroup, 3 developed new skeletal metastases. No cases showed any wound-related problems in the post-operative period. The authors concluded that transfusion of intraoperatively salvaged blood did not result in disseminated metastatic cancer. They suggested that red cell salvage might have a role during metastatic spine surgery. The findings of this small, pilot study (n = 10) need to be validated by well-designed studies.

Kumar and colleagues (2014) stated that intra-operative cell salvage (IOCS) has been used in musculoskeletal surgery extensively. However, it has never found its place in musculoskeletal oncologic surgery. These investigators conducted the first-ever study to evaluate the feasibility of IOCS in combination with a LDF in metastatic spine tumor surgery. This was to pave the path for use of IOCS-LDF in musculoskeletal oncologic surgery. Patients with a known primary epithelial tumor, who were offered surgery for metastatic spinal disease, were recruited. Blood samples were collected at 3 different stages during the surgery: (i) from the operative field before IOCS processing, (ii) after IOCS
processing, and (iii) after IOCS-LDF processing. Three separate samples (5 ml each) were taken at each stage. Samples were examined using immunohistochemical monoclonal antibodies to identify tumor cells of epithelial origin. Of 30 patients in the study, 6 were excluded for not fulfilling the inclusion criteria, leaving 24 patients. Malignant tumor cells were detected in the samples from the operative field before IOCS processing in 8 patients and in the samples from the transfusion bag after IOCS processing in 3 patients. No viable malignant cell was detectable in any of the blood samples after passage through both IOCS and LDF. The authors concluded that these findings support the notion that the IOCS-LDF combination works effectively in eliminating tumor cells from salvaged blood, so this technique can be applied successfully in spine tumor surgery. They stated that this concept can then further be extended to whole musculoskeletal tumor surgery and other oncologic surgeries with further appropriate clinical studies.

So-Osman et al (2014a) noted that patient blood management combines the use of several transfusion alternatives. Integrated use of erythropoietin, cell saver, and/or post-operative drain reinfusion devices on allogeneic erythrocyte (RBC) use was evaluated using a restrictive transfusion threshold. In a factorial design, adult elective hip- and knee-surgery patients with hemoglobin (Hb) levels 10 to 13 g/dL (n = 683) were randomized for erythropoietin or not, and subsequently for autologous re-infusion by cell saver or post-operative drain re-infusion devices or for no blood salvage device. Primary outcomes were mean allogeneic intra- and post-operative RBC use and proportion of transfused patients (transfusion rate). Secondary outcome was cost-effectiveness. With erythropoietin (n = 339), mean RBC use was 0.50 units (U)/patient and transfusion rate 16 % while without (n = 344), these were 0.71 U/patient and 26 %, respectively. Consequently, erythropoietin resulted in a non-significant 29 % mean RBC reduction (OR, 0.71; 95 % CI: 0.42
to 1.13) and 50 % reduction of transfused patients (OR, 0.5; 95 % CI: 0.35 to 0.75). Erythropoietin increased costs by €785 per patient (95 % CI: 262 to 1,309), that is, €7,300 per avoided transfusion (95 % CI: 1,900 to 24,000). With autologous reinfusion, mean RBC use was 0.65 U/patient and transfusion rate was 19 % with erythropoietin (n = 214) and 0.76 U/patient and 29 % without (n = 206). Compared with controls, autologous blood re-infusion did not result in RBC reduction and increased costs by €537 per patient (95 % CI: 45 to 1,030). The authors concluded that in hip- and knee-replacement patients (Hb level, 10 to 13 g/dL), even with a restrictive transfusion trigger, erythropoietin significantly avoids transfusion, however, at unacceptably high costs. Moreover, they stated that autologous blood salvage devices were not effective.

So-Osman et al (2014b) stated that patient blood management is introduced as a new concept that involves the combined use of transfusion alternatives. In elective adult total hip- or knee-replacement surgery patients, the authors conducted a large randomized study on the integrated use of erythropoietin, cell saver, and/or post-operative drain re-infusion devices (DRAIN) to evaluate allogeneic use of RBC, while applying a restrictive transfusion threshold. Patients with a pre-operative Hb level greater than 13 g/dL were ineligible for erythropoietin and evaluated for the effect of autologous blood re-infusion. Patients were randomized between autologous re-infusion by cell saver, DRAIN or no blood salvage device. Primary outcomes were mean intra- and post-operative RBC use and proportion of transfused patients (transfusion rate). Secondary outcome was cost-effectiveness. In 1,759 evaluated total hip- and knee-replacement surgery patients, the mean RBC use was 0.19 (SD, 0.9) erythrocyte units/patient in the autologous group (n = 1,061) and 0.22 (0.9) erythrocyte units/patient in the control group (n = 698) (p = 0.64). The transfusion rate was 7.7 % in the autologous group compared with 8.3 % in the control group (p = 0.19). No difference in RBC use was found between cell saver and DRAIN groups. Costs were increased
by €298 per patient (95 % CI: 76 to 520). The authors concluded that in patients with pre-operative Hb levels greater than 13 g/dL, autologous intra- and post-operative blood salvage devices were not effective as transfusion alternatives: use of these devices did not reduce RBC use and increased costs.

Miao and associates (2014) noted that posterior spinal instrumentation and fusion surgery in school-aged children and adolescents is associated with the potential for massive intra-operative blood loss, which requires significant allogeneic blood transfusion. Until now, the intra-operative use of the cell saver has been extensively adopted; however, its efficacy and cost-effectiveness have not been well established. These researchers determined the efficacy and cost-effectiveness of intra-operative cell saver use. This study was a single-center, retrospective study of 247 school-aged and adolescent patients who underwent posterior spinal instrumentation and fusion surgery between August 2007 and June 2013. A cell saver was used intra-operatively in 67 patients and was not used in 180 patients. Matched case-control pairs were selected using a propensity score to balance potential confounders in baseline characteristics. Allogeneic RBC and plasma transfusions as well as blood transfusion costs were analyzed. The propensity score matching produced 60 matched pairs. Compared to the control group, the cell saver group had significantly fewer intra-operative allogeneic RBC transfusions (p = 0.012). However, when the combined post-operative and total peri-operative periods were evaluated for the use of allogeneic RBC transfusion, no significant differences were observed between the 2 groups (p = 0.813 and p = 0.101, respectively). With regard to the total cost of peri-operative transfusion of all blood products (RBC and plasma), costs for the control group were slightly lower than those of the cell saver group, but this variance did not reach statistical significance (p = 0.095). The authors concluded that the use of the cell saver in posterior spinal instrumentation and fusion surgery in school-aged children and adolescents was
able to decrease the amount of intra-operative allogeneic RBC transfusion; but failed to decrease total peri-operative allogeneic RBC transfusion. Moreover, the use of the cell saver was not cost-effective.

Dusik et al (2014) stated that arthroplasty entails considerable exposure to allogenic blood transfusion. Cell salvage with washing is a contemporary strategy that is not universally used despite considerable potential benefits. These investigators searched Embase and Medline to determine if blood salvage with washing during primary and/or revision hip and knee arthroplasty resulted in lower rates of transfusion and post-operative complications. They included 10 studies in the analysis, which they rated according to Downs and Black criteria. With primary knee arthroplasty, there was a reduction in transfusion rate from 22 % to 76 % and a 48 % reduction in transfusion volume (n = 887). With primary hip arthroplasty, there was a reduction from 69 % to 73 % in transfusion rate and a 31 % reduction in transfusion volume (n = 239). There was a significant decrease in length of hospital stay (9.6 versus 13.6 days). Studies of revision arthroplasty reported a 31 % to 59 % reduction in transfusion volume (n = 241). The authors concluded that the available evidence demonstrated reduced exposure to allogenic blood with the use of salvage systems. Studies have been under-powered to detect differences in infection rates and other post-operative complications. Moreover, they stated that future cost analysis is warranted.

Liang and colleagues (2015) determined the safety and effectiveness of intra-operative cell salvage system in decreasing the need for allogeneic transfusions in a cohort of scoliosis patients undergoing primary posterior spinal fusion (PSF) with segmental spinal instrumentation. A total of 110 consecutive scoliosis patients undergoing PSF were randomized into 2 groups according to whether a cell saver machine for intra-operative blood salvage was used or not. Data included age, body mass index, peri-operative Hb levels,
surgical time, levels fused, peri-operative estimated blood loss, peri-operative transfusions and incidence of transfusion-related complications. A Chi-square test and t-tests were performed for intra-operative and peri-operative allogeneic transfusion between groups. A regression analysis was performed between selected covariates to investigate the predictive factors of peri-operative transfusion. Peri-operative allogenic blood transfusion rate was lower in the cell saver group (14.5 versus 32.7 %, p = 0.025). Mean intra-operative RBC transfusion requirement was also lower (0.21 U/patient versus 0.58 U/patient, p = 0.032). A multi-variate analysis demonstrated that number of fused segments (OR: 1.472; p = 0.005), pre-operative Hb level (OR: 0.901; p = 0.001), and the use of cell saver system (OR: 0.133; p = 0.003) had a trend toward significance in predicting likelihood of transfusion. The authors concluded that cell saver use significantly reduced the need for allogeneic blood in spine deformity surgery, particularly in patients with low pre-operative Hb or longer operation time. They stated that this study confirmed the utility of routine cell saver use during PSF with segmental spinal instrumentation for scoliosis patients.

CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

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<td>O44.10 - O44.13</td>
<td>Placenta previa with hemorrhage</td>
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<td>O45.001 - O45.099</td>
<td>Premature separation of placenta with coagulation defect</td>
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<td>O46.001 - O46.099</td>
<td>Antepartum hemorrhage with coagulation defect</td>
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<td>Intrapartum hemorrhage with coagulation defect</td>
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<td>Third-stage hemorrhage</td>
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<td>O72.1</td>
<td>Other immediate postpartum hemorrhage</td>
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<td>Delayed and secondary postpartum hemorrhage</td>
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<td>O90.2</td>
<td>Hematoma of obstetric wound</td>
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<td>R04.2</td>
<td>Hemoptysis</td>
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<td>R04.81</td>
<td>Acute idiopathic pulmonary hemorrhage in infants [AIPHI]</td>
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<td>R04.89</td>
<td>Hemorrhage from other sites in respiratory passages</td>
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<td>R04.9</td>
<td>Hemorrhage from respiratory passages, unspecified</td>
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<td>R58</td>
<td>Hemorrhage, not elsewhere classified</td>
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<tr>
<td>S27.0xx+ - S27.2xx+</td>
<td>Traumatic pneumothorax, hemothorax and hemopneumothorax</td>
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<td>Code Description</td>
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<td>T81.30x+</td>
<td>Disruption of wound, not elsewhere classified</td>
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<td>T81.33x+</td>
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<td>T81.710+</td>
<td>Vascular complications following a procedure, not elsewhere classified</td>
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<td>T81.72x+</td>
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<td>T86.00</td>
<td>Complications of transplanted organs and tissue</td>
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<td>T87.30</td>
<td>Other complications of amputation stump</td>
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<td>Accidental puncture or laceration during a procedure [Codes not listed due to expanded specificity]</td>
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<td>Hemorrhage complicating a procedure [Codes not listed due to expanded specificity]</td>
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The above policy is based on the following references:


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0639 Autotransfusers

There are no amendments for Medicaid.

www.aetnabetterhealth.com/pennsylvania  new 11/01/2018