

Case Number:	CM13-0043939		
Date Assigned:	12/27/2013	Date of Injury:	11/03/2005
Decision Date:	07/30/2014	UR Denial Date:	10/17/2013
Priority:	Standard	Application Received:	10/31/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The expert reviewer is Board Certified in General Surgery and is licensed to practice in California. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This male has an operation on 6/28/13. The preop diagnosis was L4-S1 spondylosis with junctional kyphotic deformity and progressive neurologic deficit, bilateral lower extremities footdrop. Estimated blood loss was 200cc. In the records provided to this reviewer is an order with an unrecognizable signature for use of a cell saver. This is dated the same day as the surgical procedure. There is not an explanation in the entire package of records provided to this reviewer that delineates medical necessity for use of a cell saver. There is not a history of a prior bleeding history. The hemoglobin is 15.4; platelet count is 169 on the same date, 6/18/2013. PT and PTT are within normal limits. The labs do not detect a protein deficiency. The past medical history is significant for hypertension, dyslipidemia, and sinus bradycardia. The procedure is an extensive one approached posteriorly and is a two-level fusion albeit much more involved than the usual "simple" posterior lumbar fusion. The literature does not support the prophylactic presence of the cell saver supplies, equipment, and technician for a lumbar fusion. The first article (2014) quoted below relates to fusion surgery for scoliosis in school-aged children and adolescents. This is germane on the basis of the conclusion: 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 intraoperative allogeneic RBC transfusion but failed to decrease total perioperative allogeneic RBC transfusion. Moreover, the use of the cell saver was not cost-effective." The second article (2013) concludes, " Body mass index, multi-level fusion and transforaminal interbody fusion result in increased use of autologous cell saver transfusion in lumbar spinal surgery. Use of autologous cell saver transfusion did not reduce the requirement for intraoperative or postoperative allogeneic blood transfusion." A third article (2004) concludes, " While the Cell Saver group did require fewer postoperative 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 predonation of autologous blood. With contemporary practices of predonation, the use of the Cell Saver appears to be neither necessary nor cost-effective during most elective lumbar fusions."

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

RETROSPECTIVE DOS 6/28/2013: ONE CELL SAVER MACHINE RENTAL: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: 1) PLoS One. 2014 Apr 1;9(4):e92997. doi: 10.1371/journal.pone.0092997. eCollection 2014. The efficacy and cost-effectiveness of cell saver use in instrumented posterior correction and fusion surgery for scoliosis in school-aged children and adolescents. Miao YL1, Ma HS2, Guo WZ3, Wu JG2, Liu Y4, Shi WZ5, Wang XP2, Mi WD5, Fang WW4.2) Spine (Phila Pa 1976). 2013 Feb 15;38(4):E217-22. doi: 10.1097/BRS.0b013e31827f044e. Predictive factors for the use of autologous cell saver transfusion in lumbar spinal surgery. Owens RK 2nd1, Crawford CH 3rd, Djurasovic M, Canan CE, Burke LO, Bratcher KR, McCarthy KJ, Carreon LY.3) Spine (Phila Pa 1976). 2004 Jul 15;29(14):1580-3; discussion 1584. The Cell Saver in adult lumbar fusion surgery: a cost-benefit outcomes study. Reitman CA1, Watters WC 3rd, Sassard WR.

Decision rationale: There is not an explanation in the entire package of records provided to this reviewer that delineates medical necessity for use of a cell saver. There is not a history of a prior bleeding history. The hemoglobin is 15.4; platelet count is 169 on the same date, 6/18/2013. PT and PTT are within normal limits. The labs do not detect a protein deficiency. The past medical history is significant for hypertension, dyslipidemia, and sinus bradycardia. The procedure is an extensive one approached posteriorly and is a two-level fusion albeit much more involved than the usual simple posterior lumbar fusion. The literature does not support the prophylactic presence of the cell saver supplies, equipment, and technician for a lumbar fusion and is therefore not medically necessary.

RETROSPECTIVE DOS 6/28/2013: ONE BLOOD FILTER: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: 1) PLoS One. 2014 Apr 1;9(4):e92997. doi: 10.1371/journal.pone.0092997. eCollection 2014. The efficacy and cost-effectiveness of cell saver use in instrumented posterior correction and fusion surgery for scoliosis in school-aged children and adolescents. Miao YL1, Ma HS2, Guo WZ3, Wu JG2, Liu Y4, Shi WZ5, Wang XP2, Mi WD5, Fang WW4.2) Spine

(Phila Pa 1976). 2013 Feb 15;38(4):E217-22. doi: 10.1097/BRS.0b013e31827f044e.Predictive factors for the use of autologous cell saver transfusion in lumbar spinal surgery.Owens RK 2nd1, Crawford CH 3rd, Djurasovic M, Canan CE, Burke LO, Bratcher KR, McCarthy KJ, Carreon LY.3) Spine (Phila Pa 1976). 2004 Jul 15;29(14):1580-3; discussion 1584.The Cell Saver in adult lumbar fusion surgery: a cost-benefit outcomes study.Reitman CA1, Watters WC 3rd, Sassard WR.

Decision rationale: The literature does not support the prophylactic presence of the cell saver supplies, equipment, and technician for a lumbar fusion. Therefore the request is not medically necessary.

RETROSPECTIVE DOS 6/28/2013: ONE BLOOD BAG: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: 1) PLoS One. 2014 Apr 1;9(4):e92997. doi: 10.1371/journal.pone.0092997. eCollection 2014.The efficacy and cost-effectiveness of cell saver use in instrumented posterior correction and fusion surgery for scoliosis in school-aged children and adolescents.Miao YL1, Ma HS2, Guo WZ3, Wu JG2, Liu Y4, Shi WZ5, Wang XP2, Mi WD5, Fang WW4.2) Spine (Phila Pa 1976). 2013 Feb 15;38(4):E217-22. doi: 10.1097/BRS.0b013e31827f044e.Predictive factors for the use of autologous cell saver transfusion in lumbar spinal surgery.Owens RK 2nd1, Crawford CH 3rd, Djurasovic M, Canan CE, Burke LO, Bratcher KR, McCarthy KJ, Carreon LY.3) Spine (Phila Pa 1976). 2004 Jul 15;29(14):1580-3; discussion 1584.The Cell Saver in adult lumbar fusion surgery: a cost-benefit outcomes study.Reitman CA1, Watters WC 3rd, Sassard WR.

Decision rationale: The literature does not support the prophylactic presence of the cell saver supplies, equipment, and technician for a lumbar fusion. Therefore the request is not medically necessary.

RETROSPECTIVE DOS 6/28/2013: ONE TRANSFUSION BLOOD OR BLOOD COMPONENTS: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: 1) PLoS One. 2014 Apr 1;9(4):e92997. doi: 10.1371/journal.pone.0092997. eCollection 2014.The efficacy and cost-effectiveness of cell saver use in instrumented posterior correction and fusion surgery for scoliosis in school-aged children and adolescents.Miao YL1, Ma HS2, Guo WZ3, Wu JG2, Liu Y4, Shi WZ5, Wang XP2, Mi WD5, Fang WW4.2) Spine (Phila Pa 1976). 2013 Feb 15;38(4):E217-22. doi: 10.1097/BRS.0b013e31827f044e.Predictive

factors for the use of autologous cell saver transfusion in lumbar spinal surgery.Owens RK 2nd1, Crawford CH 3rd, Djurasovic M, Canan CE, Burke LO, Bratcher KR, McCarthy KJ, Carreon LY.3) Spine (Phila Pa 1976). 2004 Jul 15;29(14):1580-3; discussion 1584.The Cell Saver in adult lumbar fusion surgery: a cost-benefit outcomes study.Reitman CA1, Watters WC 3rd, Sassard WR.

Decision rationale: The literature does not support the prophylactic presence of the cell saver supplies, equipment, and technician for a lumbar fusion. Therefore the request is not medically necessary.

RETROSPECTIVE DOS 6/28/2013: ONE RED BLOOD CELLS, LEUKOCYTES

REDUCED: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: 1) PLoS One. 2014 Apr 1;9(4):e92997. doi: 10.1371/journal.pone.0092997. eCollection 2014.The efficacy and cost-effectiveness of cell saver use in instrumented posterior correction and fusion surgery for scoliosis in school-aged children and adolescents.Miao YL1, Ma HS2, Guo WZ3, Wu JG2, Liu Y4, Shi WZ5, Wang XP2, Mi WD5, Fang WW4.2) Spine (Phila Pa 1976). 2013 Feb 15;38(4):E217-22. doi: 10.1097/BRS.0b013e31827f044e.Predictive factors for the use of autologous cell saver transfusion in lumbar spinal surgery.Owens RK 2nd1, Crawford CH 3rd, Djurasovic M, Canan CE, Burke LO, Bratcher KR, McCarthy KJ, Carreon LY.3) Spine (Phila Pa 1976). 2004 Jul 15;29(14):1580-3; discussion 1584.The Cell Saver in adult lumbar fusion surgery: a cost-benefit outcomes study.Reitman CA1, Watters WC 3rd, Sassard WR.

Decision rationale: The literature does not support the prophylactic presence of the cell saver supplies, equipment, and technician for a lumbar fusion. Therefore the request is not medically necessary.

RETROSPECTIVE DOS 6/28/2013: ONE RED BLOOD CELLS, WASHED: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: 1) PLoS One. 2014 Apr 1;9(4):e92997. doi: 10.1371/journal.pone.0092997. eCollection 2014.The efficacy and cost-effectiveness of cell saver use in instrumented posterior correction and fusion surgery for scoliosis in school-aged children and adolescents.Miao YL1, Ma HS2, Guo WZ3, Wu JG2, Liu Y4, Shi WZ5, Wang XP2, Mi WD5, Fang WW4.2) Spine (Phila Pa 1976). 2013 Feb 15;38(4):E217-22. doi: 10.1097/BRS.0b013e31827f044e.Predictive factors for the use of autologous cell saver transfusion in lumbar spinal surgery.Owens RK 2nd1,

Crawford CH 3rd, Djurasovic M, Canan CE, Burke LO, Bratcher KR, McCarthy KJ, Carreon LY.3) Spine (Phila Pa 1976). 2004 Jul 15;29(14):1580-3; discussion 1584.The Cell Saver in adult lumbar fusion surgery: a cost-benefit outcomes study.Reitman CA1, Watters WC 3rd, Sassard WR.

Decision rationale: The literature does not support the prophylactic presence of the cell saver supplies, equipment, and technician for a lumbar fusion. Therefore the request is not medically necessary.