# Appendix J

Points Matrix

# Appendix J: Points Matrix

## I. Introduction

Below is the methodology and criteria that will be utilized by the Claims Administrator to evaluate the claims of Qualifying Program Claimants, as set forth in Section 6.02 of the Master Settlement Agreement. The claims of all Qualifying Program Claimants will be evaluated utilizing a system based on Points. In short, each Qualifying Program Claimant will be assigned an initial number of Points ("Basis Points") which are set on a grid with variables of age and the extent of the injury determined to have been sustained ("Injury Level"). The Basis Points will then be adjusted for (1) the cumulative dosage of ACTOS Products ingested by the Qualifying Program Claimant at the time of Bladder Cancer Diagnosis ("Cumulative Dosage Adjustment"); and (2) for certain risk factors from which the Claims Administrator determines that the Qualifying Program Claimant suffered as well as other factors relating to the timing of the Qualifying Program Claimant's usage of ACTOS Products and diagnosis of Bladder Cancer ("Risk Factor and Other Adjustments").

## II. Points Matrix and Adjustments

| Basis Points | | | | | |
|---|---|---|---|---|---|
| **Injury Level** | **Age** | | | | |
| | **<50** | **50-59** | **60-69** | **70-79** | **>79** |
| **Injury Level 1** (Single occurrence; Ta or Tis low grade) | 120 | 110 | 100 | 85 | 70 |
| **Injury Level 2** (Recurrent bladder cancer; Ta or Tis high grade; T1) | 200 | 180 | 155 | 125 | 80 |
| **Injury Level 3** (Radiation and/or chemotherapy; T2) | 240 | 220 | 180 | 150 | 120 |
| **Injury Level 4** (Bladder removal or removal of kidney; T3) | 375 | 325 | 250 | 175 | 150 |
| **Injury Level 5** (Death due to bladder cancer; T4) | 750 | 500 | 400 | 325 | 225 |

| Cumulative Dosage Adjustment | |
|---|---|
| **Cumulative Dosage of ACTOS at Time of Bladder Cancer Diagnosis** | **Adjustment** |
| Less than 900 mg, and Bladder Cancer was diagnosed three years or longer after last use of ACTOS Products as documented in contemporaneous Pharmacy or Medical Records. | -90% |
| Less than 900 mg, and Bladder Cancer was diagnosed less than three years after last use of ACTOS Products as documented in contemporaneous Pharmacy or Medical Records. | -85% |
| Less than 1,800 mg | -80% |
| Less than 2,700 mg | -70% |
| Less than 5,400 mg | -60% |
| Less than 10,800 mg | -50% |
| Less than 16,200 mg | -35% |
| Less than 21,600 mg | -15% |
| Less than 28,800 mg | no adjustment |
| Less than 43,200 mg | +5% |
| Less than 56,700 mg | +10% |
| 56,700 mg and above | +20% |

| Risk Factor and Other Adjustments | |
|---|---|
| **Adjustment Category** | **Adjustment** |
| Diagnosis of Bladder Cancer Prior to ACTOS Products Use | -70% |
| ACTOS Products Usage Continuing After December 1, 2011 | -10% |
| Current Smoker (within 1 year before Bladder Cancer diagnosis) | -50% |
| Recent Smoker (stopped >1 but <5 years before Bladder Cancer diagnosis) | -25% |

| | |
|---|---|
| Former Smoker (stopped >5 but <20 years before Bladder Cancer diagnosis) | -10% |
| Symptoms of Bladder Cancer Prior to Use of ACTOS Products and within 2 years prior to Bladder Cancer diagnosis: Hematuria or Painful Urination | -25% |
| Diagnosis more than 5 years after last use of ACTOS (More than 28,800 mg cumulative dosage) | -33% |
| Diagnosis more than 5 years after last use of ACTOS (Less than 28,800 mg cumulative dosage) | -66% |
| Toxic Exposure | -50% |
| Bladder Cancer Metastasized from Other Cancers | -75% |
| Cyclophosphamide Use | -25% |
| Pelvic Radiation | -25% |

## III. Definitions and Instructions

A. Injury Levels:

1. Injury Level 1: Diagnosis of Ta or Tis, low grade (G1 or G2), Bladder Cancer, as determined by a pathology report.

   In the event that the Claim Package does not include a pathology report, but the Claims Administrator, Eligibility Committee, or Special Master, as applicable, concludes that the Eligible Claimant has sufficiently proven that he, or she, has been diagnosed with Bladder Cancer, the Claimant shall be assigned to Level 1 unless there is evidence of treatment that would warrant placement in a higher Injury Level.

2. Injury Level 2: Diagnosis of Ta or Tis, high grade (G), or T1 Bladder Cancer, or the diagnosis of a Recurrence of Bladder Cancer.

   "Recurrence" shall be defined as a reappearance of cancer in the urothelial lining of the bladder, the renal pelvis or the ureter, documented in a pathology report.

3. Injury Level 3: Diagnosis of T2 Bladder Cancer, *or* radiation therapy for the treatment of Bladder Cancer, *or* systemic (oral or intravenous) chemotherapy for the treatment of Bladder Cancer (not to include direct bladder treatments).

4. Injury Level 4: Diagnosis of T3 Bladder Cancer, *or* partial or radical Cystectomy or Nephrectomy for the treatment of Bladder Cancer.

   "Cystectomy" shall be defined as a surgical procedure to remove all or part of the urinary bladder.

"Nephrectomy" shall be defined as a surgical procedure to remove all or part of a kidney.

5. Injury Level 5: Diagnosis of T4 Bladder Cancer, *or* death from Bladder Cancer. Death from Bladder Cancer must be proven by autopsy or death certificate attributing the death to Bladder Cancer as a primary or secondary cause of the death, or by a contemporaneous medical record reflecting that a qualified medical professional has determined Bladder Cancer to be a primary or secondary cause of the death.

B. Diagnosis of Bladder Cancer prior to ACTOS Products usage:

1. Qualifying Program Claimants with a diagnosis of Bladder Cancer that pre-dates usage of ACTOS Products, but with one or multiple recurrences of Bladder Cancer diagnosed following usage of ACTOS Products, will in all cases have their claims evaluated based on Injury Level 1, as set forth in the Points Matrix.

2. For all such Qualifying Program Claimants:

a) The 70% point deduction for Diagnosis of Bladder Cancer Prior to ACTOS Products Use will be applied;
b) No further Risk Factor and Other Adjustments will be applied, except for (1) the applicable deduction or enhancement corresponding to that Claimant's Cumulative ACTOS Dosage Prior to Diagnosis, and (2) the deduction for ACTOS Products Usage Continuing After December 1, 2011, if applicable.
c) For the application of the Usage Adjustment, "Cumulative ACTOS Dosage Prior to Diagnosis" shall refer to cumulative dosage of ACTOS Products used by Claimant at the time of the first recurrence of Bladder Cancer following ACTOS Products usage;
d) For the application of the Points Matrix, "Age" will refer to the Claimant's age at the time of the first recurrence of Bladder Cancer following ACTOS Products usage;
e) Current or former smoking deductions will refer to time of the first recurrence of Bladder Cancer following ACTOS Products usage; and
f) If Claimant is deceased with a cause of death of Bladder Cancer, total Points shall be increased by 50%. Death from Bladder Cancer must be proven by autopsy or death certificate attributing the death to Bladder Cancer as a primary or secondary cause of the death, or by a contemporaneous medical record reflecting that a qualified medical professional has determined Bladder Cancer to be a primary or secondary cause of the death.

C. Age: Unless Claimant was diagnosed with Bladder Cancer prior to ACTOS Products usage, as set forth above, "Age", in application of the Points Matrix, shall refer to the age of the Product User at the time of Bladder Cancer Diagnosis.

D. Qualifying Program Claimants whom the Eligibility Committee or Special Master has deemed to have an Eligible Claim: For all Qualifying Program Claimants who have submitted deficient Claim Packages, but whom the Eligibility Committee or Special Master has deemed to have an Eligible Claim, the amount of such Qualifying Program Claimant's Point Award will be determined with reference to the highest Cumulative ACTOS Dosage Prior to Diagnosis and highest Injury Level that can be supported based on the records submitted with the Claim Packages. If the records provided with the Claim Package are not sufficient to assess whether such Qualifying Program Claimant should or should not receive any of the other Risk Factor and Other Adjustments listed herein (other than the adjustment for Cumulative ACTOS Dosage Prior to Diagnosis), at the discretion of the Claims Administrator and pursuant to guidelines to be established by the Claims Administrator, a deduction up to the maximum deduction for each category will be applied.

E. Cumulative Dosage Adjustment: The Cumulative Dosage Adjustment for each Qualifying Program Claimant shall be made with respect to the highest usage category applicable at the time of that Claimant's diagnosis of Bladder Cancer, unless otherwise set forth herein.

F. Risk Factor and Other Adjustments:

1. "Symptoms of Bladder Cancer Prior to Use of ACTOS Products and within 2 years prior to Bladder Cancer diagnosis: Hematuria or Painful Urination" shall be defined as: (1) hematuria, and/or (2) pain with urination, if experienced prior to ACTOS Products usage and within 2 years prior to diagnosis of Bladder Cancer.

2. ACTOS Products Usage Continuing After December 1, 2011: The point deduction for this category shall be applied to any Claimant who commenced use of ACTOS Products before December 1, 2011 and used ACTOS Products at any time thereafter. As set forth in Section 2.01 of the Master Settlement Agreement, only Claimants who commenced use of ACTOS Products prior to December 1, 2011 are eligible for participation in the ACTOS Resolution Program.

3. Smoking:
   a) "Current Smoker" shall be defined as a Claimant with a history of smoking within one year prior to or after Bladder Cancer diagnosis;
   b) "Recent Smoker" shall be defined as a Claimant with a history of smoking from between one and five years prior to Bladder Cancer diagnosis;
   c) "Former Smoker" shall be defined as a Claimant with a history of smoking more than five years but less than twenty years prior to Bladder Cancer diagnosis.

   If there is uncertain or contradictory evidence in Claim Package documentation regarding the categorization of a Claimant into one of the

smoking categories listed above (or such Claimant's categorization as a non-smoker), the Claims Administrator shall assign such Claimant into the smoking category most favorable to the Claimant that may be reasonably supported based on the totality of the Claim Package documentation.

4. Toxic Exposure: The adjustment for Toxic Exposure shall be applied as to a particular Claimant if there is a reference in such Claimant's Core Medical Records suggesting a causal association of Claimant's Bladder Cancer diagnosis with:

   a) History of exposure to coal gasification, diesel engine exhaust, iron or steel foundries, coke, coal tar, carbon black, or shale oil extraction, wood impregnation, roofing, road paving, chimney sweeping, aluminum, carbon electrodes, or the production of rubber, leather, textiles, dyes, or paint products; and/or
   b) Past work as painter, hairdresser, machinist, printer, or truck driver.

5. Bladder Cancer Metastasized from Other Cancers: The point deduction for this category shall be applied to any Claimant where it is determined that the Claimant's Bladder Cancer originated in another organ and subsequently metastasized or spread to the bladder.

6. "Cyclophosphamide Use" shall be defined as the use of any pharmaceutical product containing the active pharmaceutical compound cyclophosphamide, including the branded medication known as "Cytoxin."

7. "Pelvic Radiation" shall be defined as a history of radiation therapy to the pelvis prior to a diagnosis of Bladder Cancer, including for, but not limited to, the treatment of prostate, uterine, cervical, rectal or anal cancer.

8. Diagnosis more than 5 years after last use of ACTOS (More than 28,800 mg cumulative dosage): The point deduction for this category shall be applied to any Claimant where it is determined that Claimant's Bladder Cancer was first diagnosed five years or more after the Claimant's last use of ACTOS Products as documented in contemporaneous Pharmacy or Medical Records, **and**, the Claimant's cumulative dosage of ACTOS products ingested prior to Bladder Cancer diagnosis was greater than or equal to 28,800 mg.

9. Diagnosis more than 5 years after last use of ACTOS (Less than 28,800 mg cumulative dosage): The point deduction for this category shall be applied to any Claimant where it is determined that Claimant's Bladder Cancer was first diagnosed five years or more after the Claimant's last use of ACTOS Products as documented in contemporaneous Pharmacy or Medical Records, **and**, the Claimant's cumulative dosage of ACTOS products ingested prior to Bladder Cancer diagnosis was less than 28,800 mg.